

**EPA Registration Number 75341-16**

**Jacket # 9294403**

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling. Shake before using. Dilute 1 gallon of this concentrate with 1 1/2 gallons of water. If diluted product is to be used or stored at temperatures near or below 32°F (0°C) dilute 1 gallon of this concentrate with 3/4 of a gallon (2840 ml) of water and 1/4 of a gallon (2840 ml) of propylene glycol to prevent freezing. Shake or stir well before using.

**Internal Treatment:** Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening. Apply one gallon (maximum per cu. ft. of wood) or to refusal.

**Surface Treatment:** ORD-X021 can also be applied by brush or roller to protect wood surfaces or end-cuts. Use one coat on materials to be finished with paint or stain. If no finish is to be used, apply two liberal coats within the hour. Thoroughly cover ends.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**TICIDE STORAGE:** Store in a secure, well-ventilated area protected from extreme temperatures. Do not transfer to unmarked containers. Keep container closed when not in use.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent) promptly after emptying. Puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**DRUMS:** Residue Removal: Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat the procedure two more times. Offer for reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**CONTAINERS 5 GALLONS OR LESS:** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, New York 14209  
EPA Est. 3008-NY-1  
E.P.A. Registration No. 75341-xx

switch places

INDUSTRIAL USE ONLY. NOT FOR HOUSEHOLD USE

ORD-X021

ACTIVE INGREDIENTS:

Copper Ethanolamine Complex\*..... 14.61%  
(CAS No. 14215-52-2).  
Disodium Octaborate Tetrahydrate ..... 12.5%  
Inert Ingredients..... All caps ..... 72.89%  
TOTAL 100.00%  
please

\*Equivalent to 5% Copper as Metal

FOR EXTERIOR USE ONLY  
KEEP OUT OF REACH OF CHILDREN  
CAUTION

disposed

FIRST AID

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed:	Call poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Probable muscosal damage may contraindicate the use of gastric lavage.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
To report complaints, or in case of accidents or medical emergencies involving this product, call CHEMTREC at 1-800-424-9300.	

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS: \_\_\_\_\_

BATCH NO: \_\_\_\_\_

DESCRIPTION

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment

Applicators and other handlers must wear eye protection, such as goggles or face shield, and chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, vitro). Mixers, loaders, applicators, and other handlers must wear the following: long-sleeve shirt or protective sleeves, long pants, shoes plus socks. Protective clothing must be changed when it shows signs of contamination. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

User Safety Recommendations

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

JUN-2012

**TASK ASSIGNMENT FORM**  
**Antimicrobial Division/Regulatory Management Branches**

<b>ORIGINATOR/PRODUCT REVIEWER:</b>		Tom Luminello, Jr		<b>RMB II TEAM</b> <u>34</u>			
<b>Decision No:</b> 467215		<b>Submission No:</b> 920019		<b>EPA File Symbol/Reg No.</b>			
<b>PRIA Fee:</b> \$ <u>4631</u>		<b>Action Code:</b> A540		<b>75341-RA</b>			
<b>GPRA:</b>	<b>FQPA</b>	<b>Non-FQPA</b>		<b>Product Re-reg.</b>			
<b>PRIA:</b>	<b>ME-TOO</b> X	<b>New Use</b> <input type="checkbox"/>	<b>Old Chemical</b>	<b>New Chemical</b> <input type="checkbox"/>	<b>Amend w/data</b>		
		<b>MONTH</b>	<b>DAY</b>	<b>YEAR</b>			
<b>APPLICATION DATE</b>		6	10	2012			
<b>EPA PIN DATE</b>		7	12	2012			
<b>DATE PM RECEIVED FROM FRONT END</b>				2012			
<b>DATE SENT TO SCIENCE</b>				2012			
<b>DATE RECEIVED FROM SCIENCE</b>							
<b>NEGOTIATED DUE DATE</b>				<b>DATE DUE OUT OF AGENCY</b>			
<b>Type of Data:</b>	<b>PSB Product Chemistry</b> x	<b>PSB Acute Toxicology</b>	<b>PSB Efficacy</b>	<b>RASSB Environmental Fate</b>	<b>RASSB Ecological Effects</b>	<b>RASSB Chronic Toxicology</b>	<b>RASSB Exposure/Residue</b>

**Comments:** Please provide hard and electronic copy of deliverable(s).

**New Wood Preservative Registration**(Please Present at Next PRIA Meeting)

**Product Chemistry:** Please review Copper ethanolamine complex/Boron Sodium oxide basic and alternate CSFs and Product Chemistry data in MRIDs 48884601 and 48884602

**Acute Toxicology:** Please review data in MRID 48879603 and 48879608

**Note:** I think the action code should be A550 because this is a wood preservative registration. I am conferring w/ Dennis on this; however, he is out of the office until Monday.

define "Bore-hole" as Bore hole into wood

# DATA PACKAGE BEAN SHEET

Date: 24-Jul-2012

Page 1 of 2

Decision #: 467215

DP #: (403966)

PRIA

Parent DP #:

Submission #: 920019

E-Sub #:

## \*\*\* Registration Information \*\*\*

Registration: 75341-RA - ORD-X021

Company: 75341 - OSMOSE UTILITIES SERVICES, INC.

Risk Manager: RM 34 - Jacqueline Campbell-McFarlane - (703) 308-6416 Room# PY1 S-82

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date:

PRIA Due Date: 07-Dec-2012

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: 024409, Copper ethanolamine complex(14.61%)

011107, Boron sodium oxide (B3Na2O13) (12008-41-2)(12.5%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☒ Yes ☐ No

Date Sent: 24-Jul-2012

Due Back:

DP Ingredient: 011107, Boron sodium oxide (B3Na2O13) (12008-41-2)

024409, Copper ethanolamine complex

DP Title: Product Chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

### Assigned To

### Date In

### Date Out

Organization: AD / PSB

Last Possible Science Due Date: 07-Nov-2012

Team Name: CTT

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

New Wood Preservative Product

Please review the chemistry data in MRID 48884601 thru 48884602



## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling. Shake before using. Dilute 1 gallon of this concentrate with 1 1/4 gallons of water. If diluted product is to be used or stored at temperatures near or below 32°F (0°C): dilute 1 gallon of this concentrate with 3/4 of a gallon (2840 ml) of water and 3/4 of a gallon (2840 ml) of propylene glycol to prevent freezing. Shake or stir well before using.

**Internal Treatment:** Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening. Apply one gallon (maximum per cu. ft. of wood) or to refusal.

**Surface Treatment:** ORD-X021 can also be applied by brush or roller to protect wood surfaces or end-cuts. Use one coat on materials to be finished with paint or stain. If no finish is to be used, apply two liberal coats within the hour. Thoroughly cover ends.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**TICIDE STORAGE:** Store in a secure, well-ventilated area protected from extreme temperatures. Do not transfer to unmarked containers. Keep container closed when not in use.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent) promptly after emptying. Puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**DRUMS:** Residue Removal: Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat the procedure two more times. Offer for reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**CONTAINERS 5 GALLONS OR LESS:** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, New York 14209  
EPA Est. 3008-NY-1  
E.P.A. Registration No. 75341-xx

switch places

INDUSTRIAL USE ONLY. NOT FOR HOUSEHOLD USE

# ORD-X021

## ACTIVE INGREDIENTS:

Copper Ethanolamine Complex*.....	14.61%
(CAS No. 14215-52-2).	
Disodium Octaborate Tetrahydrate .....	12.5%
Inert Ingredients.....	72.89%
TOTAL	100.00%

\*Equivalent to 5% Copper as Metal

## FOR EXTERIOR USE ONLY KEEP OUT OF REACH OF CHILDREN CAUTION

## FIRST AID

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed:	Call poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.  Probable mucosal damage may contraindicate the use of gastric lavage.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
To report complaints, or in case of accidents or medical emergencies involving this product, call CHEMTREC at 1-800-424-9300.	

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS: \_\_\_\_\_

BATCH NO: \_\_\_\_\_

DE

ORD-X021 is designed for remedial treatment of posts, beams, lumber, bridge and mine timbers.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS

**CAUTION:** Harmful if swallowed or absorbed. Prolonged or frequently repeated skin contact. Avoid contact with skin, eyes or clothing. Before eating, drinking, chewing gum, or using tobacco, remove contaminated clothing before reuse.

## Personal Protective Equipment

Applicators and other handlers must wear chemical-resistant gloves (such as barrier gloves made of polyvinyl chloride, nitrile, or neoprene). Mixers, loaders, and applicators should wear long-sleeved shirts and long pants, and protective sleeves, if changed when it shows signs of deterioration. Wash face, hands, and exposed skin after cleaning/maintaining PPE. If no such washing facilities are available, use water. Keep and wash PPE separately from other material that have been drenched or heavily soiled.

## User Safety Requirements

Follow manufacturer's instructions for use. Washables exist, use detergent and hot water. Discard clothing and other absorbent materials with the product's concentrate. Do not reuse them.

## User Safety Recommendations

Users must wash hands before eating, drinking, or using tobacco. Users must remove clothing/PPE immediately after use. Users must remove as possible, wash thoroughly and change clothes.

## ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to lakes, streams, ponds, estuaries, or other bodies of water. If the requirements of a National Pollutant Discharge Elimination Act (NPDES) permiting authority has been notified in writing, this product to sewer system authority. For guidance, contact your State or local health department.

ent of in-service poles, poles and poletops, bore holes, ers and piling.

ed through the skin.. Causes moderate eye irritation.  
lact may cause allergic reactions in some individuals.  
/ash thoroughly with soap and water after handling and  
ing tobacco or using the toilet. Remove and wash

eye protection, such as goggles or face shield, and laminate, butyl rubber, nitrile rubber, neoprene rubber, applicators, and other handlers must wear the following: pants, shoes plus socks. Protective clothing must be decontaminated. Follow manufacturer's instructions for cleaning. If instructions for washables exist, use detergent and hot water. Discard clothing and other absorbent materials heavily contaminated with the product's concentrate. Do not

cleaning/maintaining PPE. If no such instructions for  
ter. Keep and wash PPE separately from other laundry.  
erial that have been drenched or heavily contaminated  
se them.

inking, chewing gum, using tobacco, or using the toilet. Immediately if pesticide gets inside. Then wash thoroughly and remove PPE immediately after handling this product. As soon as possible, change into clean clothing. Wash the outside of gloves before

c organisms. Do not discharge effluent containing this  
ries, oceans or public waters unless in accordance with  
Discharge Elimination System (NPDES) permit and the  
writing prior to discharge. Do not discharge effluent  
without previously notifying the sewage treatment plant  
Water Board or Regional Office of the EPA.

JUN-2012

# Material Sent for Data Extraction

REG # 75341-16

Description: Amendment

Material (s) Sent to Data Extraction Contractors

- ☒ New Stamped label Dated: 7/31/2014
- ☐ Notification Dated:
- ☐ New CSF(s) Dated:
- ☐ Other:

Decision #:

491449

---

Other Action/Comments:

---

---

Reviewer: Lorena Rivas

Phone: 703-305-5027

Division: AD

Date: July 31, 2014

***Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).***

**TASK ASSIGNMENT FORM**  
**Antimicrobial Division/Regulatory Management Branches**

<b>ORIGINATOR/PRODUCT REVIEWER: Lorena Rivas</b>						<b>RMB II TEAM</b> ____34____	
<b>Decision No: 491449</b>			<b>Submission No: 951906</b>			<b>EPA File Symbol/Reg No.</b> 75341-16	
<b>PRIA Fee: \$</b> _____			<b>Action Code: 302</b>				
<b>GPRA:</b>	<b>FQPA</b>		<b>Non-FQPA</b>		<b>Product Re-reg.</b>		
<b>PRIA:</b>	<b>ME-TOO</b>	<b>New Use</b> <input type="checkbox"/>	<b>Old Chemical</b>	<b>New Chemical</b> <input type="checkbox"/>	<b>Amend w/data</b>		
		<b>MONTH</b>	<b>DAY</b>	<b>YEAR</b>			
<b>APPLICATION DATE</b>		<b>5</b>	<b>2</b>	<b>2014</b>			
<b>EPA PIN DATE</b>		<b>5</b>	<b>6</b>	<b>2014</b>			
<b>DATE PM RECEIVED FROM FRONT END</b>				<b>2014</b>			
<b>DATE SENT TO SCIENCE</b>				<b>2014</b>			
<b>DATE RECEIVED FROM SCIENCE</b>							
<b>NEGOTIATED DUE DATE</b>				<b>DATE DUE OUT OF AGENCY</b>		<b>8/4/14</b>	
<b>Type of Data:</b>	<b>PSB Product Chemistry</b>	<b>PSB Acute Toxicology</b>	<b>PSB Efficacy</b>	<b>RASSB Environmental Fate</b>	<b>RASSB Ecological Effects</b>	<b>RASSB Chronic Toxicology</b>	<b>RASSB Exposure/Residue</b>
<p><b>Comments:</b> Please provide hard and electronic copy of deliverable(s).</p> <p>Label Amendment: Please review label. Registrant is changing signal word from "CAUTION to WARNING."</p>							



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

Teri Muchow  
Manager-Regulatory Administration  
Osmose Utilities services, Inc.  
980 Ellicott Street  
Buffalo, NY 14209

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

JUL 31 2014

Subject: ORD-X021  
EPA Registration Number: 75341-16  
Application Date: May 02, 2014  
Receipt Date: May 06, 2014

Dear Ms. Muchow:

The following label amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA) 3(c) 7(A), as amended, is **acceptable**.

**Proposed Amendment**

Change the signal word on the label from "CAUTION" to "WARNING".

**General Comments**

A stamped accepted label is enclosed for your records. This labeling supersedes all previous labeling. The next printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed label before selling or distributing the product bearing the revised labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling, or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at [campbell.jacqueline@epa.gov](mailto:campbell.jacqueline@epa.gov) or Lorena Rivas by telephone at (703) 305-5027 or by email at [rivas.loreana@epa.gov](mailto:rivas.loreana@epa.gov). When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,

Jacqueline Hardy  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosure: Stamped label



INDUSTRIAL USE. NOT FOR HOUSEHOLD USE

## ORD-X021

ACTIVE INGREDIENTS:

Copper Ethanolamine Complex*.....	14.61%
(CAS No. 14215-52-2).	
Disodium Octaborate Tetrahydrate .....	12.50%
INERT INGREDIENTS.....	72.89%
TOTAL	100.00%

\*Equivalent to 5% Copper as Metal

**FOR EXTERIOR USE ONLY**  
**KEEP OUT OF REACH OF CHILDREN**

### WARNING

#### FIRST AID

If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If swallowed:	Call poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Probable muscosal damage may contraindicate the use of gastric lavage.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

To report complaints, or in case of accidents or medical emergencies involving this product, call CHEMTREC at 1-800-424-9300.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Osmose Utilities Services, Inc.

215 Greencastle Road

Tyrone, GA 30290-2944

E.P.A. Registration No. 75341-16

EPA Est. xxxxx

NET CONTENTS:

☐ 16 ounces    ☐ 1 gallon    ☐ 4 gallon    ☐ 5 gallon    ☐ 55 gallon

BATCH NO: \_\_\_\_\_

**ACCEPTED**

7/31/2014

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 75341-16

## DESCRIPTION

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling.

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Causes skin irritation. Harmful if inhaled. Avoid breathing vapor. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get on skin or on clothing. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

#### Personal Protective Equipment

Applicators and other handlers must wear eye protection, such as goggles or face shield, and chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, vitro). Mixers, loaders, applicators, and other handlers must wear the following: long-sleeve shirt or protective sleeves, long pants, shoes plus socks. Protective clothing must be changed when it shows signs of contamination. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

#### User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.

## ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling. ORD-X021 halts existing wood decay and protects against future decay.

*(for 1, 4, 5 and 55 gallon containers)*

Shake before using. Dilute 1 gallon of this concentrate with 1 ½ gallons of water. If diluted product is to be used or stored at temperatures near or below 32°F (0°C), dilute 1 gallon of this concentrate with ¾ of a gallon (2840 ml) of water and ¾ of a gallon (2840 ml) of propylene glycol to prevent freezing. Shake or stir well before using.

*(for 16 ounce containers only)*

To dilute contents of 16 oz container, add water to fill to base of bottle neck. If diluted product is used or stored at temperatures below 32°F (0°C), dilute with a 50/50 mix of water and propylene glycol to prevent freezing. Shake well before using.

**Internal Treatment:** Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening. Apply one gallon (maximum per cu. ft. of wood) or to refusal.

**Surface Treatment:** ORD-X021 can also be applied by brush or roller to protect wood surfaces or end-cuts. Use one coat on materials to be finished with paint or stain. If no finish is to be used, apply two liberal coats within the hour. Thoroughly cover ends.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in a secure, well-ventilated area protected from extreme temperatures. Do not transfer to unmarked containers. Keep container closed when not in use.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent) promptly after emptying. Puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**DRUMS:** Residue Removal: Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container  $\frac{1}{4}$  full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat the procedure two more times. Offer for reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**CONTAINERS 5 GALLONS OR LESS:** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container  $\frac{1}{4}$  full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

MAY-2014

## Rivas, Lorena

---

**From:** Muchow, Teri <tmuchow@osmose.com>  
**Sent:** Thursday, August 07, 2014 2:43 PM  
**To:** Rivas, Lorena  
**Subject:** RE: Accept Amendment for Reg. 75341-16

Lorena

I received your email and the attachment.

Teri Muchow  
Manager - Regulatory Administration  
Osmose, Inc.  
1016 Everee Inn Road  
Griffin, GA 30224  
ph: (770) 233-4244  
fx: (770) 229-5225  
tmuchow@osmose.com

---

**From:** Rivas, Lorena [mailto:Rivas.Lorena@epa.gov]  
**Sent:** Thursday, August 07, 2014 2:05 PM  
**To:** Muchow, Teri  
**Subject:** Accept Amendment for Reg. 75341-16

Hello Ms. Muchow,

Enclosed you will find the scan copy of the approved Amendment Agency letter plus, copy of the stamped label dated July 31, 2014,  
for Registration No. 75341-16.  
Please verify with an email that you received all the attachments.

If you have any questions regarding this email, or the Amendment response do not hesitate to contact me.

Have a great day

Regards,

Lorena Rivas  
Antimicrobials Division (AD)  
Team 34  
Regulatory Management Branch II  
[Rivas.lorena@epa.gov](mailto:Rivas.lorena@epa.gov)

May 2, 2014

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Re: ORD-X021, EPA Reg. No. 75341-16  
Amendment of Signal Word

Dear Sir/Madam:

Enclosed is an application for the amendment of the product label for ORD-X021, EPA Reg. No. 75341-16, to change the signal word on the label from "CAUTION" to "WARNING". While the product was assigned a toxicity category III classification, the reviewer of the dermal irritation study assigned it toxicity category II. A copy of the DER is attached. A subsequent review by the California Department of Pesticide Registration (CDPR) also resulted in a toxicity category II classification. A change in the product label is required before CDPR will grant registration.

The precautionary statements on the label already include reference to skin irritation as well as the need for corresponding personal protective equipment, therefore the only change being made to the label is the signal word. Enclosed are five copies of a marked up label and one copy of a "clean" label.

If you have any questions regarding the enclosed, please contact me. I may be reached by phone at 770-233-4244 or by email at [tmuchow@osmose.com](mailto:tmuchow@osmose.com).

Sincerely,



Teri Muchow  
Manager  
Regulatory Administration





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 8, 2012

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 75341-RA  
Data Package 403967  
Product Name: ORD-X021

From: Wallace Powell, Biologist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

*Wallace Powell*

Through: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

*Karen Hicks*

To: Jacqueline Campbell, PM 34/ Tom Luminello  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Applicant: Osmose Utilities Services, Inc.

FORMULATION FROM PROPOSED LABEL:

<u>Active Ingredients:</u>	<u>% by weight</u>
Copper ethanolamine complex	14.61
Disodium octaborate tetrahydrate	12.50
<u>Other Ingredient(s):</u>	<u>72.89</u>
Total:	100.00

BACKGROUND

In support of registration of the subject product ORD-X021, EPA File Symbol 75341-RA, the applicant has submitted studies for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, eye irritation, skin irritation, and skin sensitization – MRIDs 488846-03 through -08, respectively.

## RECOMMENDATION

The submitted studies are acceptable. The resulting acute Toxicity Categories are listed in the table below.

### Summary:

The acute toxicity profile of ORD-X021 is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	488846-03	III	Acceptable
Acute Dermal Toxicity	488846-04	IV	Acceptable
Acute Inhalation Toxicity	488846-05	III	Acceptable
Primary Eye Irritation	488846-06	III	Acceptable
Primary Skin Irritation	488846-07	II	Acceptable
Dermal Sensitization	488846-08	Sensitizer	Acceptable

## PRODUCT LABELING

The following comments refer to the proposed draft label dated by applicant "JUN-2012" (EPA received 7/12/2012).

### Revisions:

The following changes should be made to the "Hazards to Humans and Domestic Animals" statements, in accordance with the *Label Review Manual*:

1. Add the statement: "Causes skin irritation."
2. Add: "Harmful if inhaled. Avoid breathing vapor."
3. Change the skin portion of the statement "Avoid contact with skin, eyes or clothing" so that it reads: "Do not get on skin or on clothing. Avoid contact with eyes." (An alternative would be: "Do not get in eyes, on skin or clothing.")

The following statements should be added to the First Aid section:

#### If inhaled:

Move person to fresh air.

If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

Call a poison control center or doctor for further treatment advice.

In the First Aid section, the "If on skin" instructions should be listed first. (The *Label Review Manual* states: "First Aid statements should be organized so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first.")

Other comments:

The statements for Personal Protective Equipment and for User Safety appear acceptable in light of existing Reregistration Eligibility Decision (RED) documents (the *Boric Acid* and *Coppers* REDs).

The Reregistration Eligibility Decision (RED) for *Coppers* contains a "General Application Restrictions for products with WPS or non-WPS uses on the label," to be placed in the Directions for Use (following the misuse statement). The Agency Product Manager may determine whether that statement is applicable and required:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation."

Information regarding the product (ORD-X021) has been entered into the Label Review System (LRS). The resulting sample labeling for the product in LRS is available for internal reference.

## DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OPPTS 870.1100)

**Product Manager:** 34  
**MRID No.:** 488846-03

**Reviewer:** W. Powell  
**Study Completion Date:** 4/19/2012  
**Report No.:** 33786

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Shaken prior to dosing.)

**Dosage:** 175, 550, and 2,000 mg/kg

**Species:** Rat, Sprague-Dawley derived

**Sex:** 8 Females (nulliparous and non-pregnant)

**Age:** 8-11 weeks

**Weight:** 165-205 g

**Source:** Harlan Laboratories, Inc.

**Method:** Up-and-Down Procedure

### Summary:

1. **Estimated LD<sub>50</sub>:** 2,000 mg/kg
2. **Toxicity Category:** III
3. **Classification:** Acceptable

**Deviations from Guideline 870.1100:** None noted.

### Results:

The test substance was administered by oral gavage to eight female rats, in the sequence listed in the table below. Five reversals occurred in the last six animals tested, thus a stopping rule was met. The three decedent animals died within three hours after test substance administration.

A single dose was associated with partial response. This was the highest test dose, with no responses at all other test doses. This scenario corresponds to Case # 5 of Table 8 in section (m)(3) of the OPPTS 870.1100 Guidelines. Based on the AOT425 software (Westat, May 2001) and the above scenario, the results indicate an acute oral LD<sub>50</sub> of 2,000 mg/kg. 95% PL Confidence Interval: 665.7 mg/kg to 4,540 mg/kg.

### Reported Mortality

Dosing Sequence	Animal No.	Dose Level (mg/kg)	Short-Term Outcome	Long-Term Outcome
1	3101	175	S	S
2	3102	550	S	S
3	3103	2,000	S	S
4	3104	2,000	D	D
5	3105	550	S	S
6	3106	2,000	D	D
7	3107	550	S	S
8	3108	2,000	D	D

S = Survival, D = Death



## DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

**Product Manager:** 34  
**MRID No.:** 488846-04

**Reviewer:** W. Powell  
**Study Completion Date:** 4/11/2012  
**Report No.:** 33787

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Mixed prior to dosing. Dosed as received.)  
**Dosage:** 5,000 mg/kg

**Species:** Rat, Sprague-Dawley derived  
**Sex:** 5 Males, 5 Females (nulliparous and non-pregnant)  
**Age:** 9-10 weeks  
**Weight:** Males 252-268 g, Females 181-195 g  
**Source:** Harlan Laboratories, Inc.

### Summary:

1. **Estimated LD<sub>50</sub>:** > 5,000 mg/kg
2. **Toxicity Category:** IV
3. **Classification:** Acceptable

**Deviations from Guideline 870.1200:** None noted.

### Results:

Administration of the test substance by dermal application at a dose of 5,000 mg per kg body weight to male and female rats produced no mortality during the 14-day observation period. The results indicate that the dermal LD<sub>50</sub> of the sample was greater than 5,000 mg/kg in male and female rats. Clinical signs observed were limited to dermal irritation (erythema), small areas of eschar and/or blanching, and green staining. Necropsy revealed no gross abnormalities. All animals showed weekly weight gain.

### Reported Mortality

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Combined
5,000	0 / 5	0 / 5	0 / 10

## DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)

**Product Manager:** 34  
**MRID No.:** 488846-05

**Reviewer:** W. Powell  
**Study Completion Date:** 4/19/2012  
**Report No.:** 33788

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Shaken prior to dispensing and kept on a magnetic stirrer.)

**Concentration:** Gravimetric = 2.10 mg/L, Nominal = 32.06 mg/L. (Nose-only exposure)

**Species:** Rat, Sprague-Dawley derived

**Sex:** 5 Males, 5 Females (nulliparous and non-pregnant)

**Age:** 9-10 weeks

**Weight:** Males 256-273 g, Females 175-190 g

**Source:** Harlan Laboratories

### Summary:

1. **LC<sub>50</sub> (mg/L):** > 2.10 mg/L in male rats,  
> 0.5 mg/L in female rats
2. **Average MMAD:** 2.31  $\mu$ m
3. **Toxicity Category:** III
4. **Classification:** Acceptable

### Deviations from Guideline 870.1300:

1. After what appeared to be compound-related mortality in two females occurred at one dose concentration, a second concentration was not tested. (Refer to *Results* below for further details.)
2. It appears that the total volume of the animals was greater than 5% of the chamber volume. However, in view of the plentiful airflow rate, this is not a concern.

### Results:

Two (of five) females died. The one was found dead approximately 3.5 hours post-exposure; the other was euthanized for humane reasons. The other 3 females and all 5 males survived the 14-day observation period.

Following exposure, all animals exhibited irregular respiration. Several exhibited hypoactivity and rales (moist). In addition, one of the two decedents exhibited tremors, and the other exhibited ataxia, proneness, gasping, and moribund appearance. The surviving animals recovered from the reported symptoms at various times ranging from Day 2 to Day 10.

Necropsy findings were unremarkable except in the two decedents. In one of the decedents was found discoloration and distension of the stomach and intestines and darkened spots on the liver and kidneys. In the other decedent was found discoloration of the lungs.

Based on the reported mortality, the median lethal concentration is estimated to be greater than 2.10 mg/L in male rats. However, in female rats the median lethal concentration is considered undetermined, though for regulatory categorization it is being considered greater than 0.5 mg/L (as a worst case).

In order to qualify as a limit test, mortality should be limited to no more than one animal in either sex. This study is no exception, as the two deaths in the female seem compound-related. The ORD-X021 study, then, does not qualify as a limit test. I.e., we cannot assign 2.10 mg/L as the LC<sub>50</sub> lower limit or place the test material in Toxicity Category IV for acute inhalation. Category III is assigned as worst case (as a Category II outcome would be very unlikely).

#### Reported Mortality

Exposure Concentration (mg/L)	Number of deaths / number tested		
	Males	Females	Combined
2.10	0 / 5	2 / 5	2 / 10

#### Chamber Atmosphere

Exposure Conc. (mg/L)	MMAD (µm)	GSD (µm)	% of Particles ≤ 4.7 µm
2.10	2.31	2.29	82.8

#### Chamber Environment

Exposure Level (mg/L)	2.10
Chamber Volume, approx. (L)	28
Total Airflow Rate (Lpm)	31.6
Temperature in exposure tube (°C)	19 - 20
Relative Humidity in exposure tube (%)	26 - 32

## DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

**Product Manager:** 34  
**MRID No.:** 488846-06

**Reviewer:** W. Powell  
**Study Completion Date:** 4/19/2012  
**Report No.:** 33789

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Shaken prior to dosing.)

**Dosage:** 0.1 mL

**Species:** Rabbit, New Zealand albino  
**Sex:** 3 females (nulliparous and non-pregnant)  
**Age:** Young adult  
**Weight:** Not reported  
**Source:** Robinson Services, Inc.

### Summary:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

**Deviations from Guideline 870.2400:** The study report did not state that the lids of the treated eye were held together for about 1 second following test substance instillation. (However, the Study Director Carolyn Lowe told the reviewer on 10/22/2012 that this procedural step is always taken.)

### Results:

Corneal opacity (of low degree, grade 1 on the Draize scale) and 'positive' conjunctival redness and swelling (both of grade 2), were observed in two of three rabbits at 1 hour, and positive conjunctival redness in one of three rabbits at 24 hours. All such signs cleared in all rabbits by 48 hours. No iridal involvement or other positive signs were observed during the 72-hour observation period.

### Incidence of Irritation

Time Post-Instillation	No. of Animals Testing "Positive" / No. of Animals Tested			
	Corneal Opacity	Iritis	Conjunctiva	
			Redness	Chemosis
1 hour	0 / 3	0 / 3	3 / 3	3 / 3
24 hours	1 / 3	0 / 3	1 / 3	0 / 3
48 hours	0 / 3	0 / 3	0 / 3	0 / 3
72 hours	0 / 3	0 / 3	0 / 3	0 / 3

## DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OPPTS 870.2500)

**Product Manager:** 34  
**MRID No.:** 488846-07

**Reviewer:** W. Powell  
**Study Completion Date:** 4/19/2012  
**Report No.:** 33790

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Shaken prior to dosing.)  
**Dosage:** 0.5 mL

**Species:** Rabbit, New Zealand albino  
**Sex:** 3 females (nulliparous and non-pregnant)  
**Age:** Young adult  
**Weight:** Not reported  
**Source:** Robinson Services, Inc.

### Summary:

1. **Toxicity Category:** II
2. **Classification:** Acceptable

**Deviations from Guideline 870.2500:** None noted.

### Results:

Two of three animals showed very slight erythema and no edema. Erythema in the third animal was well-defined at 30 to 60 minutes after patch removal and was severe from 24 hours through Day 7. In this animal, a small area of eschar was observed at the dose site from 24 hours through Day 7, and desquamation was observed at the dose site on Days 7 and 10.

The Guidelines define the skin irritation Toxicity Category in terms of the effects at 72 hours. In view of that, and in view of the small number of animals tested, and the severity of response in animal 3503 and its lack of improvement until late in the study, a strong emphasis is being placed on animal 3503. The severe irritation in that animal cleared after Day 7. In view of all this, Toxicity Category II is assigned (even though the study report states that the requirements of Category IV were met, a conclusion that may have been based in large part on the Primary Irritation Index).



### Individual Skin Irritation Scores

Animal No.	Sex	Erythema / Edema					
		Time After Patch Removal					
		30-60 min	24 hrs	48 hrs	72 hrs	Day 7	Day 10
3501	F	1 / 0	1 / 0	0 / 0	0 / 0	0 / 0	0 / 0
3502	F	1 / 0	1 / 0	0 / 0	0 / 0	0 / 0	0 / 0
3503	F	2 / 1 <sup>1</sup>	4 / 2 <sup>2</sup>	4 / 1 <sup>2</sup>	4 / 1 <sup>2</sup>	4 / 1 <sup>2,3</sup>	0 / 0 <sup>3</sup>

<sup>1</sup> Blue discoloration in the dose site

<sup>2</sup> Small area of eschar in the dose site

<sup>3</sup> Desquamation present at the dose site

## DATA REVIEW FOR SKIN SENSITIZATION TESTING (OPPTS 870.2600)

**Product Manager:** 34  
**MRID No.:** 488846-08

**Reviewer:** W. Powell  
**Study Completion Date:** 4/10/2012  
**Report No.:** 33791

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021 (a dark blue liquid)  
**Positive Control Material:** alpha-Hexylcinnamaldehyde

**Species:** Mouse, CBA/J, Female  
**Weight:** 18.7-23.3 g (Test and Control groups)  
**Age:** 10-11 weeks (Test and Control groups), 9-10 weeks (Preliminary animals)  
**Source:** Harlan Laboratories, Inc.

**Method:** Local Lymph Node Assay

### Summary:

1. ORD-X021 appeared to be a contact sensitizer.
2. **Classification:** Acceptable

### Deviations from Guideline 870.2600:

- Temperature in the animal room slightly exceeded the Guidelines.
- Based on body weights reported, it appears that the Vehicle Control and Positive Control animals were the same as those used in Product Safety Labs study 33785 (MRID 488852-08, reviewed in Data Package 404722). Presumably this is because (as appears to be the case) the two studies were conducted concurrently and the Vehicle Control and Positive Control substances appear appropriate for both studies. Thus the sharing of these animals between the two studies was appropriate.

### Procedure:

Five female mice were selected for one Test Substance group. (No further Test Substance groups were treated, presumably because this group showed a positive response.) On Days 1, 2, and 3, 25 µL of a 25% concentration of the test substance in propylene glycol was applied to the dorsum of both ears of each test animal. A Vehicle Control group (5 females) was treated in the same way as the Test Substance group, but with vehicle alone (propylene glycol). A Positive Control group (5 females) was treated with 25% alpha-hexylcinnamaldehyde in propylene glycol. The test sites in all three groups were evaluated for local irritation (erythema & edema) on Days 1, 2, 3, and 6. Body weights were taken on Days 1 and 6.

On Day 6, the animals in all three groups were injected in the tail vein with 250  $\mu$ L of phosphate buffered saline (PBS) containing 20  $\mu$ Ci of  $^3$ H-methyl thymidine. Approximately five hours after the injection, the draining auricular lymph nodes were excised and pooled for each mouse.

A single cell suspension of lymph node cells was prepared in PBS by massaging the lymph nodes between frosted ends of two microscope slides over a collection vessel. The contents of the vessel were transferred to a centrifuge tube, washed with an excess of PBS, and centrifuged for approximately 10 minutes at 1800 rpm. This wash and centrifuge was carried out twice. The supernatant was decanted and discarded following each centrifugation. After the second wash, approximately 5 mL of 5% trichloroacetic acid (TCA) was added to the sediment and the tube was briefly vortexed. The DNA was then precipitated in the TCA at approximately 4.1-4.2  $^{\circ}$ C for approximately 18 hours. The tubes were centrifuged again. The resulting precipitate was re-suspended in TCA and transferred to 10 mL of scintillation fluid. Incorporation of  $^3$ H-methyl thymidine was measured by B-scintillation counting and expressed as disintegrations per minute (DPM) minus background DPM.

### Results:

Stimulation Index (SI) for Test Substance group and for Positive Control group was derived by dividing the average net DPM of each group by the average net DPM of the Vehicle Control group, where "net DPM" is the measured DPM minus the background DPM.

Animal Group	Test Substance Concentration	Average Net DPM	Number of Mice	SI
Vehicle Control	N/A	965.39	5	N/A
Positive Control	N/A	4713.56	5	4.88
Test Substance	25%	8927.23	5	9.25

An SI far greater than 3.0 was observed in the Test Substance group, thus indicating that ORD-X021 tested positive for dermal sensitization. Note: Only slight skin irritation effects were observed in the Test Substance group. The Positive Control group tested positive.



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

<b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> Other	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 75341-16		2. EPA Product Manager Jacqueline Hardy	
4. Company/Product (Name) ORD-X021		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Osmose Utilities Services, Inc. 215 Greencastle Road Tyrone, GA 30290-2944 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<b>Section - II</b>			
<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.) Requesting permission to change the signal word on the label from "CAUTION" to "WARNING" based on the agency's review of the Acute Irritation Study.			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted If "Yes" Unit Packaging wgt.    No. per container		If "Yes" Package wgt    No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Not for retail sale.	
5. Location of Label Directions <input type="checkbox"/>		6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other pressure sensitive vinyl	
<b>Section - IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Teri Muchow		Title Manager - Regulatory Administration Telephone No. (Include Area Code) 770-233-4244	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <b>(Stamped)</b>
2. Signature 		3. Title Manager - Regulatory Administration	
4. Typed Name Teri Muchow		5. Date May 2, 2014	

Create/Edit CollectionsUtilitiesQuery ToolFatalHelpExit

S: 951906Milestone Email:

Regulatory Type: Product Registration - Section 3Resubmission: YesNoFee For Service: YesNoBillable: YesNo

Application Type: Amendment

Company: 75341 OSMOSE UTILITIES SERVICES, INC.

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 75341-16Product Name: ORD-X021

Override:

Me TooSection3:Me Too ProductName:

Application Date: 02-May-2014OPP Rec'd Date: 06-May-2014

Front End Date: 06-May-2014Risk Manager Send Date: 08-May-2014

FFS Due Date:Negotiated Due Date:

OPP Target Date:

Fast Track:New Ingredient:

Receipt Description:AMENDMENT

Form A:Signature Date:Form B:Signature Date:

Print LetterEnter More InformationTracking

Receipt ContentPaper LabelView/Edit

New IngredientRequest Date:New IngredientReceived Date:

Laena  
[302]

# Material Sent for Data Extraction

Reg. # 75341-16

Description: \_\_\_\_\_

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated 7-31-13; 9-4-12

☐ Other: \_\_\_\_\_

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Tom Luminello

Phone: 308-8075 Division: AD

Date: 11-5-13





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

NOV 11 2013

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

Teri Muchow, Manager Regulatory Administration  
Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, NY 14209-2398

Subject: ORD-X021  
EPA Registration Number 75341-16  
Amendment Date: August 1, 2013

Dear Ms. Muchow:

The Agency has reviewed your amendment submitted in accordance with continuing registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, and determined the action to be acceptable. In summary, your request to revise the basic and 2 alternate Confidential Statements of Formula (CSF) has been reviewed and approved. The revised basic CSF dated July 31, 2013 and the 2 revised alternate CSFs (CSF#2 and #3) dated September 4, 2012 (all three pin-punched August 5, 2013) supersede and replace the previously approved versions of those CSFs. A copy of our review (414396) of your chemistry submissions is enclosed.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075 or [Luminello.Tom@EPA.GOV](mailto:Luminello.Tom@EPA.GOV).

Sincerely,

Jacqueline Hardy  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

October 29, 2013

DP BARCODE: D414396

MRID:

SUBJECT: ORD-X021

REG. NO. OR FILE SYMBOL: 75341-16

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes): 024409, 011103

CAS Number: 14215-52-2, 12280-03-4

TEST LAB:

SUBMITTER: Osmose Utilities Services, Inc.

GUIDELINE:

COMMODITIES: Formulation

REVIEWER: Chris Jiang

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 10/29/13

COMMENT:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

October 29, 2013

**MEMORANDUM**

**Subject:** Review for 75341-16

**From:** Chris Jiang, Chemist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

*Chris Jiang*  
*10/29/13*

**Thru:** Karen P. Hicks, CT Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

*Juan Negron*  
*for* *10/29/13*  
*K. P. H.*

**To:** Jacqueline Hardy PM 34/Thomas Luminello, Jr.  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

**Applicant:** Osmose Utilities Services, Inc.

**Formulation from Label**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Copper ethanolamine complex (CAS No. 14215-52-2)	14.61
Disodium octaborate tetrahydrate	12.50
<u>Inert Ingredients</u>	72.89
Total	100.00
Equivalent to 5% copper as metal	

## **BACKGROUND:**

The registrant has submitted a cover letter, a Material Safety Data Sheet, and Confidential Statements of Formula for the basic formulation and alternate formulations to add an additional source of [REDACTED] to this non-integrated end-use product for non-food-use.

## **FINDINGS:**

1. The concentrations of the active ingredients on the Confidential Statements of Formula (CSFs dated July 31, 2013 for the basic formulation (CSF #1) and alternate formulations (CSFs #2 and #3) are consistent with the label declaration. These CSFs supersede all previous CSFs for the respective formulations.
2. All ingredients are approved for non-food use in pesticidal products.
3. The certified limits for all components are based on EPA standard certified limits and are **acceptable**.

## **CONCLUSIONS:**

Product Science Branch of Antimicrobials Division finds the CSFs dated July 31, 2013 for the basic formulation (CSF #1) and alternate formulations (CSFs #2 and #3) for 75341-16 to be acceptable for product chemistry.



August 1, 2013

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

**CONFIDENTIAL**

Re: ORD-X021, EPA Reg. # 75341-16  
Notification of New Source of Inert Ingredient AND  
Alternate Manufacturer

Dear Sir/Madam:

Enclosed is the notification of an alternate source of an inert ingredient [REDACTED] and an alternate manufacturer for the product ORD-X021 (EPA Reg. No. 75341-16). In support of this notification, enclosed are the following:

1. Application for Pesticide Registration/Amendment,
2. Two (2) copies of the revised CSF,
3. Material Safety Data Sheet.

Note that there are currently a basic and one alternate CSF approved for this product. Enclosed are a basic and two alternate CSFs. The reason for this is the basic CSF is now a "clean" CSF with no alternate suppliers included. This has resulted in a need for one more additional alternate CSF. There have been no changes made to the CSFs except those indicated by this notification.

If you have any questions regarding the enclosed, please contact me. I may be reached by phone at (770) 233-4244 or by email at [tmuchow@osmose.com](mailto:tmuchow@osmose.com).

Sincerely,

A handwritten signature in cursive script that reads "Teri Muchow".

Teri Muchow  
Manager -  
Regulatory Administration





**TASK ASSIGNMENT FORM**  
**Antimicrobial Division/Regulatory Management Branches**

<b>ORIGINATOR/PRODUCT REVIEWER:</b> Tom Luminello		<b>RMB II TEAM</b> 34	
<b>Decision No:</b>		<b>Submission No:</b> 939236	
<b>PRIA Fee:</b> \$		<b>Action Code:</b> 362	
<b>EPA File Symbol/Reg No.</b> 75341-16			
<b>GPRA:</b>	<b>FQPA</b>	<b>Non-FQPA</b>	<b>Product Re-reg.</b>
<b>PRIA:</b>	<b>ME-TOO</b>	<b>New Use</b> <input type="checkbox"/>	<b>Old Chemical</b>
		<b>New Chemical</b> <input type="checkbox"/>	<b>Amend w/data</b>
	<b>MONTH</b>	<b>DAY</b>	<b>YEAR</b>
<b>APPLICATION DATE</b>	8	1	2013
<b>EPA PIN DATE</b>	8	5	2013
<b>DATE PM RECEIVED FROM FRONT END</b>			2013
<b>DATE SENT TO SCIENCE</b>			2013
<b>DATE RECEIVED FROM SCIENCE</b>			
<b>NEGOTIATED DUE DATE</b>			<b>DATE DUE OUT OF AGENCY</b>
<b>Type of Data:</b>	<b>PSB Product Chemistry</b>	<b>PSB Acute Toxicology</b>	<b>PSB Efficacy</b>
	X		
		<b>RASSB Environmental Fate</b>	<b>RASSB Ecological Effects</b>
		<b>RASSB Chronic Toxicology</b>	<b>RASSB Exposure/Residue</b>
<b>Comments: Please provide hard and electronic copy of deliverable(s).</b> Minor Formulation change Pls review basic and 2 alternate CSFs - alternate source of <span style="background-color: black; color: black;">XXXXXXXXXX</span> - alternate manufacturer			

\*Inert ingredient information may be entitled to confidential treatment\*



Use read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

<b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input checked="" type="checkbox"/> <b>Other</b>	OPP Identifier Number _____
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 75341-16		2. EPA Product Manager Jacqueline Campbell	
4. Company/Product (Name) ORD-X021		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Osmose Utilities Services, Inc. 980 Ellicott Street Buffalo, NY 14209  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	
<b>Section - II</b>			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.)  Notification of alternate manufacturer AND alternate source of an inert ingredient. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt.    No. per container	If "Yes" Package wgt    No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Not for retail sale	
5. Location of Label Directions <input type="checkbox"/> _____ on container...		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
<input checked="" type="checkbox"/> Other pressure sensitive vinyl			
<b>Section - IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Teri Muchow		Title Manager - Regulatory Administration	
		Telephone No. (Include Area Code) 770 233-4244	
<b>Certification</b>  I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped)
2. Signature 		3. Title Manager - Regulatory Administration	
4. Typed Name Teri Muchow		5. Date August 1, 2013	

# Material Sent for Data Extraction

Reg. # 75341-16

Description: \_\_\_\_\_

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☒ Notification Dated 4-2-13

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Tom Lominello

Phone: 308-8075 Division: AD

Date: 4-11-13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

April 2, 2013

Teri Muchow, Manager Regulatory Administration  
Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, NY. 14209-2398

Subject: ORD-X021  
EPA Registration Number 75341-16  
Notification Date: March 7, 2013  
Notification Pin Punch: March 11, 2013

Dear Ms. Muchow:

This acknowledges receipt of your Notification submitted in accordance with the provisions of PR Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c) 9.

**Proposed Notification**

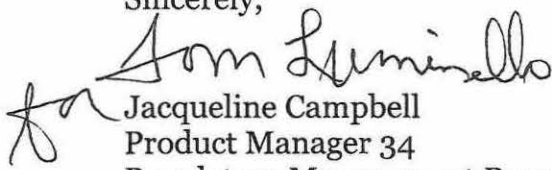
- Addition of a 16 ounce container with dilution use directions.

**General Comment**

- Based on a review of the material submitted, the Notification is acceptable.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075 or [Luminello.Tom@EPA.GOV](mailto:Luminello.Tom@EPA.GOV).

Sincerely,

  
Jacqueline Campbell  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

March 7, 2013

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Re: ORD-X021, EPA Reg. # 75341-16  
Notification of New Directions For Use Language

Dear Sir/Madam:

Enclosed is the notification of revised Directions for Use to include dilution directions for a 16 ounce container. There has been no change in the dilution ratio. In support of this notification, enclosed are the following:

1. Application for Pesticide Registration/Amendment
2. One copy of the product label with the changes clearly marked.

If you have any questions regarding the enclosed, please contact me. I may be reached by phone at (770) 233-4244 or by email at [tmuchow@osmose.com](mailto:tmuchow@osmose.com).

Sincerely,



Teri Muchow  
Manager -  
Regulatory Administration





<b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input checked="" type="checkbox"/> <b>Other</b>	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number <b>75341-16</b>		2. EPA Product Manager <b>Jacqueline McFarlane</b>	
4. Company/Product (Name) <b>ORD-X021</b>		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) <b>Osmose Utilities Services, Inc.</b> <b>980 Ellicott Street</b> <b>Buffalo, NY 14209</b> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<b>Section - II</b>			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.) Notification of new dilution instructions for use with new package size (16 ounce) as per PR Notice 98-10 (II.M.1). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted If "Yes" Unit Packaging wgt.    No. per container		If "Yes" Package wgt    No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <b>Not for retail sale.</b>	
5. Location of Label Directions <input type="checkbox"/> on container		6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other <b>pressure sensitive vinyl</b>	
<b>Section - IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name <b>Teri Muchow</b>		Title <b>Manager - Regulatory Administration</b> Telephone No. (Include Area Code) <b>771-233-4244</b>	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <b>(Stampcd)</b>
2. Signature 		3. Title <b>Manager - Regulatory Administration</b>	
4. Typed Name <b>Teri Muchow</b>		5. Date <b>March 7, 2013</b>	



INDUSTRIAL USE. NOT FOR HOUSEHOLD USE

## ORD-X021

### ACTIVE INGREDIENTS:

Copper Ethanolamine Complex\* ..... 14.61%

(CAS No. 14215-52-2).

Disodium Octaborate Tetrahydrate ..... 12.50%

INERT INGREDIENTS..... 72.89%

TOTAL 100.00%

\*Equivalent to 5% Copper as Metal

### FOR EXTERIOR USE ONLY KEEP OUT OF REACH OF CHILDREN CAUTION

#### FIRST AID

If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If swallowed:	Call poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Probable mucosal damage may contraindicate the use of gastric lavage.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
To report complaints, or in case of accidents or medical emergencies involving this product, call CHEMTREC at 1-800-424-9300.	

#### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Osmose Utilities Services, Inc.

980 Ellicott Street

Buffalo, New York 14209

E.P.A. Registration No. 75341-16

EPA Est. 3008-NY-1

#### NET CONTENTS:

☐ 16 ounces    ☐ 1 gallon    ☐ 4 gallon    ☐ 5 gallon    ☐ 55 gallon

BATCH NO: \_\_\_\_\_

## DESCRIPTION

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Causes skin irritation. Harmful if inhaled. Avoid breathing vapor. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get on skin or on clothing. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

### Personal Protective Equipment

Applicators and other handlers must wear eye protection, such as goggles or face shield, and chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, vitro). Mixers, loaders, applicators, and other handlers must wear the following: long-sleeve shirt or protective sleeves, long pants, shoes plus socks. Protective clothing must be changed when it shows signs of contamination. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

### User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.

## ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling. ORD-X021 halts existing wood decay and protects against future decay.

(for 1, 4, 5 and 55 gallon containers)

Shake before using. Dilute 1 gallon of this concentrate with 1 ½ gallons of water. If diluted product is to be used or stored at temperatures near or below 32°F (0°C), dilute 1 gallon of this concentrate with ¾ of a gallon (2840 ml) of water and ¾ of a gallon (2840 ml) of propylene glycol to prevent freezing. Shake or stir well before using.

(for 16 ounce containers only)

To dilute contents of 16 oz container, add water to fill to base of bottle neck. If diluted product is used or stored at temperatures below 32°F (0°C), dilute with a 50/50 mix of water and propylene glycol to prevent freezing. Shake well before using.

**Internal Treatment:** Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening. Apply one gallon (maximum per cu. ft. of wood) or to refusal.

**Surface Treatment:** ORD-X021 can also be applied by brush or roller to protect wood surfaces or end-cuts. Use one coat on materials to be finished with paint or stain. If no finish is to be used, apply two liberal coats within the hour. Thoroughly cover ends.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in a secure, well-ventilated area protected from extreme temperatures. Do not transfer to unmarked containers. Keep container closed when not in use.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent) promptly after emptying. Puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**DRUMS:** Residue Removal: Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container  $\frac{1}{4}$  full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat the procedure two more times. Offer for reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**CONTAINERS 5 GALLONS OR LESS:** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container  $\frac{1}{4}$  full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

NOV-2012March-2013

**TASK ASSIGNMENT FORM**  
**Antimicrobial Division/Regulatory Management Branches**

ORIGINATOR/PRODUCT REVIEWER: <i>Tom Luminello</i>				RMB II TEAM <u>34</u>			
Decision No: <i>477041</i>		Submission No: <i>932142</i>		EPA File Symbol/Reg No.			
PRIA Fee: \$ _____		Action Code: <i>332</i>		<i>75341-16</i>			
GPRA:	FQPA	Non-FQPA			Product Re-reg.		
PRIA:	ME-TOO	New Use <input type="checkbox"/>	Old Chemical	New Chemical <input type="checkbox"/>	Amend w/data		
		MONTH	DAY	YEAR			
APPLICATION DATE		<i>3</i>	<i>7</i>	2013			
EPA PIN DATE		<i>3</i>	<i>11</i>	2013			
DATE PM RECEIVED FROM FRONT END				2013			
DATE SENT TO SCIENCE				2013			
DATE RECEIVED FROM SCIENCE							
NEGOTIATED DUE DATE				DATE DUE OUT OF AGENCY		<i>4/10/2013</i>	
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/Residue

**Comments: Please provide hard and electronic copy of deliverable(s).**

*NOTIFICATION: New dilution instructions for new package size*  
*Pls review the label*

**Receipt for Section 3**

S: 932142      Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3      Fee For Service: ☐ Yes ☒ No

Application Type: Notification



Company: 75341 OSMOSE UTILITIES SERVICES, INC. **V**



Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 75341-16      Product Name: ORD-X021

Override#:

Me Too Section3:      Me Too Product Name:

Application Date: 07-Mar-2013       OPP Rec'd Date: 11-Mar-2013 

Front End Date: 11-Mar-2013       Risk Manager Send Date: 11-Mar-2013 

FFS Due Date:      Negotiated Due Date:

OPP Target Date:

Fast Track: ☐      New Ingredient: ☐

Receipt Description: NOTIFICATION

Form A: ☐      Signature Date:      Form B: ☐      Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

View/Edit

Receipt Content      Des

Paper Label

Print Letter

Enter More Information

Tracking

# Material Sent for Data Extraction

Reg # 75341-16

Description: Notification

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☒ Notification Dated 2/6/13

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☒ Decision #: 474036

☐ Other Action/Comments: \_\_\_\_\_

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: J. Rivas

Phone: \_\_\_\_\_ Division: AD

Date: 2/6/13

Created February 3, 2011



**TASK ASSIGNMENT FORM**  
Antimicrobial Division/Regulatory Manager. ranches

<b>ORIGINATOR/PRODUCT REVIEWER:</b> <i>Lorena Rivas</i>				<b>RMB II TEAM</b> <u>34</u>			
<b>Decision No:</b> <i>474036</i>		<b>Submission No:</b> <i>929324</i>		<b>EPA File Symbol/Reg No.</b>			
<b>PRIA Fee: \$</b> _____		<b>Action Code:</b> <i>332</i>		<i>75341-16</i>			
<b>GPRA:</b>	<b>FQPA</b>	<b>Non-FQPA</b>			<b>Product Re-reg.</b>		
<b>PRIA:</b>	<b>ME-TOO</b>	<b>New Use</b> <input type="checkbox"/>	<b>Old Chemical</b>	<b>New Chemical</b> <input type="checkbox"/>	<b>Amend w/data</b>		
		<b>MONTH</b>	<b>DAY</b>	<b>YEAR</b>			
<b>APPLICATION DATE</b>		<i>1</i>	<i>10</i>	<i>2012</i>			
<b>EPA PIN DATE</b>		<i>1</i>	<i>14</i>	<i>2012</i>			
<b>DATE PM RECEIVED FROM FRONT END</b>				<i>2012</i>			
<b>DATE SENT TO SCIENCE</b>				<i>2012</i>			
<b>DATE RECEIVED FROM SCIENCE</b>							
<b>NEGOTIATED DUE DATE</b>				<b>DATE DUE OUT OF AGENCY</b>		<i>2/13/2013</i>	
<b>Type of Data:</b>	<b>PSB Product Chemistry</b>	<b>PSB Acute Toxicology</b>	<b>PSB Efficacy</b>	<b>RASSB Environmental Fate</b>	<b>RASSB Ecological Effects</b>	<b>RASSB Chronic Toxicology</b>	<b>RASSB Exposure/Residue</b>

**Comments:** Please provide hard and electronic copy of deliverable(s).

*NOTIFICATION: Please review alternate brand name, Hollow Heart CB*

February 06, 2013

Teri Muchow  
 Manager-Regulatory Administration  
 Osmose Utilities Services, Inc.  
 980 Ellicott Street  
 Buffalo, NY 14209

Subject: ORD-X021  
 EPA Registration No.: 75341-16  
 Notification Date: January 10, 2013  
 EPA Receipt Date: January 14, 2013

Dear Ms. Muchow,

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA section 3(c) 9 and PR Notice 98-10.

#### Proposed Notification

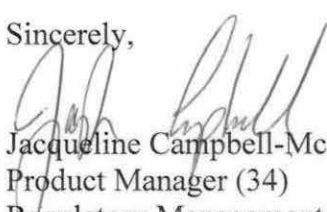
- Adding alternate brand name: HOLLOW HEART CB

#### General Comments

Based on a review of the submitted materials, adding alternate brand name Hollow Heart CB per PR Notice 98-10 is **acceptable** and apart of the record on file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at [campbell-mcfarlane.jacqueline@epa.gov](mailto:campbell-mcfarlane.jacqueline@epa.gov) or Lorena Rivas by telephone at (703) 305-5027 or by e-mail at [rivas.lorena@epa.gov](mailto:rivas.lorena@epa.gov). When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

  
 Jacqueline Campbell-McFarlane  
 Product Manager (34)  
 Regulatory Management Branch II  
 Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL	7510P						
SURNAME	Rivas						
DATE	2/06/13						



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

**OFFICE OF PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES**

**February 8, 2013**

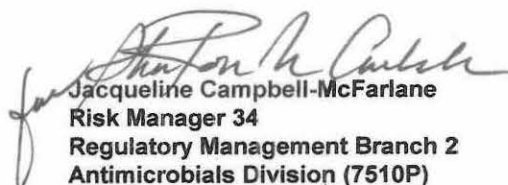
I, Jacqueline Campbell-McFarlane, Regulatory Management Branch 2, Antimicrobials Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Belize) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

**Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, NY 14209**

**EPA Registration Number: 75341-16  
Name of Product: ORD-X021**

  
**Jacqueline Campbell-McFarlane  
Risk Manager 34  
Regulatory Management Branch 2  
Antimicrobials Division (7510P)**





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES

February 8, 2013

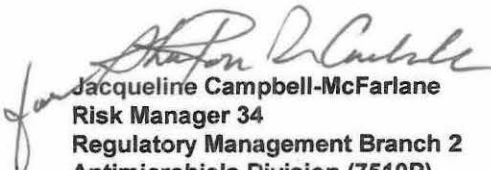
I, Jacqueline Campbell-McFarlane, Regulatory Management Branch 2, Antimicrobials Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Jamaica) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, NY 14209

EPA Registration Number: 75341-16  
Name of Product: ORD-X021

  
Jacqueline Campbell-McFarlane  
Risk Manager 34  
Regulatory Management Branch 2  
Antimicrobials Division (7510P)





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

**OFFICE OF PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES**

**February 8, 2013**

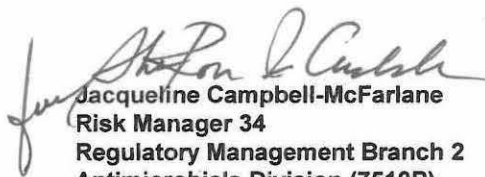
I, Jacqueline Campbell-McFarlane, Regulatory Management Branch 2, Antimicrobials Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Barbados) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, NY 14209

EPA Registration Number: 75341-16  
Name of Product: ORD-X021

  
Jacqueline Campbell-McFarlane  
Risk Manager 34  
Regulatory Management Branch 2  
Antimicrobials Division (7510P)





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

**OFFICE OF PREVENTION,  
PESTICIDES AND  
TOXIC SUBSTANCES**

**February 8, 2013**

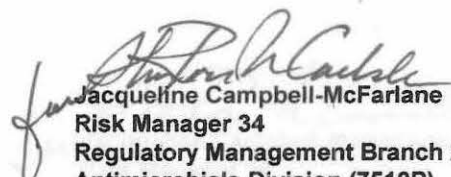
I, Jacqueline Campbell-McFarlane, Regulatory Management Branch 2, Antimicrobials Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., St. Lucia) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

**Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, NY 14209**

**EPA Registration Number: 75341-16  
Name of Product: ORD-X021**

  
**Jacqueline Campbell-McFarlane  
Risk Manager 34  
Regulatory Management Branch 2  
Antimicrobials Division (7510P)**



**Receipt for Section 3**

S: 930485      Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3      Fee For Service: ☒ Yes ☐ No

Application Type: Amendment      Billable: ☒ Yes ☐ No

Company: 75341 OSMOSE UTILITIES SERVICES, INC. **V**

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 75341-16      Product Name: ORD-X021

Override#:

Me Too Section3:       Me Too Product Name:

Application Date: 30-Jan-2013 **ie**      OPP Rec'd Date: 04-Feb-2013 **ie**

Front End Date: 04-Feb-2013 **ie**      Risk Manager Send Date: 06-Feb-2013 **ie**

FFS Due Date:       Negotiated Due Date:

OPP Target Date:

Fast Track: ☐      New Ingredient: ☐

Receipt Description:  
Gold Seal Certificate

Form A: ☐      Signature Date:       Form B: ☐      Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Print Letter

Enter More Information

Tracking

Receipt Content		Des
Other		Gold Seal

View/Edit





January 10, 2013

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Re: ORD-X021  
EPA Reg. No. 75341-16  
Notification of Alternate Brand Name

Dear Sir/Madam:

In accordance with PR Notice 98-10, enclosed is the notification of an alternate brand name for the product ORD-X021, EPA Reg. No. 75341-16.

Alternate Brand Name: **HOLLOW HEART CB**

If you have any questions, please contact me. I may be reached by phone at (770) 233-4244 or by email at [tmuchow@osmose.com](mailto:tmuchow@osmose.com).

Sincerely,

A handwritten signature in dark ink, appearing to read "Teri Muchow", is written over a horizontal line.

Teri Muchow  
Manager -  
Regulatory Administration



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input checked="" type="checkbox"/> <b>Other</b>	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number <b>75341-16</b>		2. EPA Product Manager <b>Jacqueline McFarlane</b>	
4. Company/Product (Name) <b>ORD-X021</b>		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) <b>Osmose Utilities Services, Inc.</b> <b>980 Ellicott Street</b> <b>Buffalo, NY 14209</b> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<b>Section - II</b>			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.) Notification of alternate brand name "Hollow Heart CB" as per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>* Certification must be submitted</b>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt.    No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt    No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <b>Not for retail sale.</b>	
5. Location of Label Directions <input type="checkbox"/>		6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other <u>pressure sensitive vinyl</u>	
<b>Section - IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name <b>Teri Muchow</b>		Title <b>Manager - Regulatory Administration</b>	
		Telephone No. (Include Area Code) <b>770-233-4244</b>	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <b>(Stamped)</b>
2. Signature		3. Title <b>Manager - Regulatory Administration</b>	
4. Typed Name <b>Teri Muchow</b>		5. Date <b>January 10, 2013</b>	



SCRIPTION

medial treatment of in-service poles, poles and poletops, and mine timbers and piling.

NARY STATEMENTS  
IS AND DOMESTIC ANIMALS

orbed through the skin. Caused moderate eye irritation. Avoid breathing vapor. Prolonged or frequently repeated in some individuals. Do not get on skin or on clothing. ly with soap and water after handling and before eating, or using the toilet. Remove and wash contaminated

ar eye protection, such as goggles or face shield, and r laminate, butyl rubber, nitrile rubber, neoprene rubber, applicators, and other handlers must wear the following: ng pants, shoes plus socks. Protective clothing must be intamination. Follow manufacturer's instructions for nstructions for washables exist, use detergent and hot rom other laundry. Discard clothing and other absorbent vily contaminated with the product's concentrate. Do not

leaning/maintaining PPE. If no such instructions for aier. Keep and wash PPE separately from other laundry. aterial that have been drenched or heavily contaminated use them.

rinking, chewing gum, using tobacco, or using the toilet. ately if pesticide gets inside. Then wash thoroughly and re PPE immediately after handling this product. As soon e into clean clothing. Wash the outside of gloves before

MENTAL HAZARDS

tic organisms. Do not discharge effluent containing this aries, oceans or public waters unless in accordance with Discharge Elimination System (NPDES) permit and the 1 writing prior to discharge. Do not discharge effluent ; without previously notifying the sewage treatment plant te Water Board or Regional Office of the EPA.

NOV-2012

Receipt for Section 3			
S:	929324		Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No
Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Application Type:	Notification		
Company:	75341 OSMOSE UTILITIES SERVICES, INC.		V
Risk Manager:	Antimicrobials Division, Risk Management Team 34		
Product #:	75341-16	Product Name:	ORD-X021
Overrides#:			
Me Too Section3:		Me Too Product Name:	
Application Date:	10-Jan-2013	ie	OPP Rec'd Date: 14-Jan-2013 ie
Front End Date:	15-Jan-2013	ie	Risk Manager Send Date: 15-Jan-2013 ie
FFS Due Date:			Negotiated Due Date:
OPP Target Date:			
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>
Receipt Description:		View/Edit	
Notification of Alternate Brand Name		New Ingredient Request Date	
		New Ingredient Received Date	
Form A:	<input type="checkbox"/>	Signature Date:	
Form B:	<input type="checkbox"/>	Signature Date:	

Print Letter  
 Enter More Information  
 Tracking

Receipt Content	Des
Paper Label	

# Material Sent for Data Extraction

Reg. # 75341-16

Description: New Registration

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated NOV 16 2012

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Tom Luminello

Phone: 308-8075 Division: AD

Date: NOV 16 2012





U.S. ENVIRONMENTAL PROTECTION  
AGENCY

Office of Pesticide Programs  
Antimicrobials Division (7510-P)  
1200 Pennsylvania Avenue N.W.  
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

75341-16

Date of

Issuance:

Nov. 16, 2012

Term of Issuance:

Unconditional

Name of Pesticide Product:

ORD-X021

Name and Address of Registrant (include ZIP Code):

Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, NY. 14209

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision No. 467215) is unconditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and, submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Change EPA File Symbol 75341-RA to EPA Registration Number 75341-16.
3. You must submit acceptable product specific Corrosion Characteristics and Storage Stability data within a year of this Registration notice.

Copies of our review of your Acute Toxicity data and your Product Chemistry data including your proposed Basic and Alternate Confidential Statements of Formula are enclosed.

Submit one copy of the finished final printed label prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the unconditionally approved label is enclosed for your records.

Signature of Approving Official:

*Jacqueline Campbell*  
Jacqueline Campbell  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510-P)

Date:

November 16, 2012



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

HOLLOW HEART CB is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling. HOLLOW HEART CB halts existing wood decay and protects against future decay.

Shake before using. Dilute 1 gallon of this concentrate with 1 ½ gallons of water. If diluted product is to be used or stored at temperatures near or below 32°F (0°C), dilute 1 gallon of this concentrate with ¾ of a gallon (2840 ml) of water and ¼ of a gallon (2840 ml) of propylene glycol to prevent freezing. Shake or stir well before using.

**Internal Treatment:** Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening. Apply one gallon (maximum per cu. ft. of wood) or to refusal.

**Surface Treatment:** HOLLOW HEART CB can also be applied by brush or roller to protect wood faces or end-cuts. Use one coat on materials to be finished with paint or stain. If no finish is to be used, apply two liberal coats within the hour. Thoroughly cover ends.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in a secure, well-ventilated area protected from extreme temperatures. Do not transfer to unmarked containers. Keep container closed when not in use.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent) promptly after emptying. Puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**DRUMS:** Residue Removal: Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, turning at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat the procedure two more times. Offer for reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**CONTAINERS 5 GALLONS OR LESS:** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, New York 14209  
E.P.A. Registration No. 75341-16  
EPA Est. 3008-NY-1

INDUSTRIAL USE. NOT FOR HOUSEHOLD USE

HOLLOW HEART CB

ACTIVE INGREDIENTS:

Copper Ethanolamine Complex\* ..... 14.61%  
(CAS No. 14215-52-2).

Disodium Octaborate Tetrahydrate ..... 12.50%

INERT INGREDIENTS..... 72.89%

TOTAL ..... 100.00%

\*Equivalent to 5% Copper as Metal

FOR EXTERIOR USE ONLY  
KEEP OUT OF REACH OF CHILDREN  
CAUTION

FIRST AID

If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If swallowed:	Call poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Probable muscosal damage may contraindicate the use of gastric lavage.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
To report complaints, or in case of accidents or medical emergencies involving this product, call CHEMTREC at 1-800-424-9300.	

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS:

☐ 1 gallon    ☐ 5 gallon    ☐ 55 gallon

BATCH NO: \_\_\_\_\_

DESCRIPTION

HOLLOW HEART CB is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Causes skin irritation. Harmful if inhaled. Avoid breathing vapor. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get on skin or on clothing. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment

Applicators and other handlers must wear eye protection, such as goggles or face shield, and chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, vitro). Mixers, loaders, applicators, and other handlers must wear the following: long-sleeve shirt or protective sleeves, long pants, shoes plus socks. Protective clothing must be changed when it shows signs of contamination. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

NOV-2012

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling. ORD-X021 halts existing wood decay and protects against future decay.

Shake before using. Dilute 1 gallon of this concentrate with 1 1/2 gallons of water. If diluted product is to be used or stored at temperatures near or below 32°F (0°C), dilute 1 gallon of this concentrate with 3/4 of a gallon (2840 ml) of water and 3/4 of a gallon (2840 ml) of propylene glycol to prevent freezing. Shake or stir well before using.

Internal Treatment: Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening. Apply one gallon (maximum per cu. ft. of wood) or to refusal.

Surface Treatment: ORD-X021 can also be applied by brush or roller to protect wood surfaces or end-cuts. Use one coat on materials to be finished with paint or stain. If no finish is to be used, apply two liberal coats within the hour. Thoroughly cover ends.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a secure, well-ventilated area protected from extreme temperatures. Do not transfer to unmarked containers. Keep container closed when not in use.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent) promptly after emptying. Puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DRUMS: Residue Removal: Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat the procedure two more times. Offer for reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONTAINERS 5 GALLONS OR LESS: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, New York 14209  
E.P.A. Registration No. 75341-xx  
EPA Est. 3008-NY-1

INDUSTRIAL USE. NOT FOR HOUSEHOLD USE

ORD-X021

ACTIVE INGREDIENTS:

Copper Ethanolamine Complex\* ..... 14.61%  
(CAS No. 14215-52-2).

Disodium Octaborate Tetrahydrate ..... 12.50%

INERT INGREDIENTS..... 72.89%

TOTAL ..... 100.00%

\*Equivalent to 5% Copper as Metal

FOR EXTERIOR USE ONLY  
KEEP OUT OF REACH OF CHILDREN  
CAUTION

FIRST AID

If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If swallowed:	Call poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Probable mucosal damage may contraindicate the use of gastric lavage.
If inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
To report complaints, or in case of accidents or medical emergencies involving this product, call CHEMTREC at 1-800-424-9300.	

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS: \_\_\_\_\_

BATCH NO: \_\_\_\_\_

DESCRIPTION

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Causes skin irritation. Harmful if inhaled. Avoid breathing vapor. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get on skin or on clothing. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment

Applicators and other handlers must wear eye protection, such as goggles or face shield, and chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, vitro). Mixers, loaders, applicators, and other handlers must wear the following: long-sleeve shirt or protective sleeves, long pants, shoes plus socks. Protective clothing must be changed when it shows signs of contamination. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

User Safety Requirements

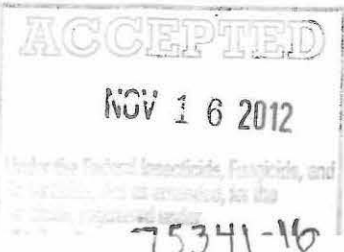
Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

NOV-2012





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

September 5, 2012

DP BARCODE: D403966

MRID: 48884601, 48884602

SUBJECT: ORD-X021

REG. NO. OR FILE SYMBOL: 75341-RA

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS (PC Codes): 024409, 011103

CAS Number: 14215-52-2, 12008-41-2

TEST LAB: Analytical & Regulatory Chemistry, Inc.

SUBMITTER: Osmose Utilities Services, Inc.

GUIDELINE: 830 Guidelines

COMMODITIES: Formulation

REVIEWER: Chris Jiang C

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 9/5/12

COMMENT:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

September 5, 2012

**MEMORANDUM**

**Subject:** Review for 75341-RA

**From:** Chris Jiang, Chemist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

**To:** Monisha Harris PM 32\Thomas Luminello, Jr.  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

**Applicant:** Osmose Utilities Services, Inc.

*Chris Jiang*  
*9/5/12*  
*[Signature]*

**Formulation from Label**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Copper ethanolamine complex *	14.61
(CAS No. 14215-52-2)	
Disodium Tebuconazole	12.5
<u>Inert Ingredients</u>	72.89
Total	100.00

\*Equivalent to 5% Copper as metal



## BACKGROUND:

The registrant has submitted a label, Confidential Statements of Formula (CSFs) for the basic formulation and an alternate formulation, and 830 Guidelines that have been identified by the Agency as MRIDs 488846201 and 488846202 to support the product chemistry requirements for this non-integrated end-use product to be used as a wood preservative. The registrant has submitted the incorrect analytical enforcement methods, has submitted the correct methods to the Agency, and has emailed the correct methods to this reviewer on August 30, 2012. This data will be submitted to attain an MRID.

## FINDINGS:

1. The concentrations of the active ingredients on the Confidential Statements of Formula (CSFs dated 9/4/2012 for the basic formulation and an alternate formulation) are consistent with the label declaration.
2. All ingredients are approved for non-food use in pesticidal products.
3. The product identity and composition is **acceptable**.
4. The description of the starting materials is **acceptable**.
5. The description of the formulation process is **acceptable**.
6. All certified limits are based on EPA standard certified limits and are **acceptable**.
7. The enforcement analytical methods that were e-mailed on August 30, 2012 are **acceptable**.
8. The color, physical state, and odor are **acceptable** as the product is a dark blue liquid with a mild odor.
9. The density is **acceptable** as this property was determined to be 1.215 g/cm<sup>3</sup> (10.1 lb/gal) at 26 °C and 1.210 g/cm<sup>3</sup> (10.1 lb/gal) at 38 °C.
10. The pH is **acceptable** as the pH of a 1% solution was determined to be 8.67.
11. The oxidation/reduction potential is **acceptable**. No change was observed when the test material was mixed with water or 5% ammonium phosphate. When the product was mixed with iron powder, the iron powder settled on the bottom. When the product was mixed with 5% potassium permanganate, the mixture changed from a brown solution to a darker brown within a minute. The temperature of the mixture also increased by 6°C. When the product was mixed with gasoline, a phase separation occurred with a clear liquid on top and a dark blue liquid on the bottom.

12. The flammability is **acceptable** as the product does not contain a flammable ingredient.
13. The explodability is **acceptable** as the product is not potentially explosive.
14. The joint study for storage stability and corrosion characteristics is ongoing.
15. The viscosity is **acceptable** as the viscosity was determined to be 5.15 centipoise at 26 °C and 3.51 centipoise at 38 °C.
16. The miscibility is **acceptable** as the product is not to be diluted with petroleum solvents.
17. The dielectric breakdown voltage is **acceptable** as the product is not to be used around electrical equipment.

#### **CONCLUSIONS:**

Product Science Branch of Antimicrobials Division finds the CSFs dated September 4, 2012 for the basic formulation and an alternate formulation and the data for 75341-RA to be acceptable, pending submission of the joint study for storage stability and corrosion characteristics.



RE: Final edits please

Muchow, Teri

to:

Tom Luminello

11/16/2012 01:44 PM

Hide Details

From: "Muchow, Teri" <tmuchow@osmose.com>

To: Tom Luminello/DC/USEPA/US@EPA

History: This message has been replied to.

1 Attachment



Label - ORD-X021 draft NOV-2012.pdf

Tom –

I made the changes you requested. Also, I am working on a similar product with Jaclyn Carl and made some label changes for her this morning that I am now incorporating into this label. On the attached I added in the Directions for Use section a statement that this product is to halt existing decay and protect against future decay. I also removed the heading "User Safety Recommendations".

If you disagree with these changes, please let me know.

Thank you,

Teri Muchow

Manager - Regulatory Administration

Osmose, Inc.

1016 Everee Inn Road

Griffin, GA 30224

ph: (770) 233-4244

fx: (770) 229-5225

tmuchow@osmose.com

file:///C:/Documents and Settings/Tluminel/Local Settings/Temp/notes87944B/~web1394.... 11/16/2012



---

**From:** Luminello.Tom@epamail.epa.gov [mailto:Luminello.Tom@epamail.epa.gov]  
**Sent:** Friday, November 16, 2012 1:23 PM  
**To:** Muchow, Teri  
**Subject:** Final edits please

(See attached file: [Untitled].pdf)

Thanks Teri for quick turnaround



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 8, 2012

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 75341-RA  
Data Package 403967  
Product Name: ORD-X021

From: Wallace Powell, Biologist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

To: Jacqueline Campbell, PM 34/ Tom Luminello  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Applicant: Osmose Utilities Services, Inc.

FORMULATION FROM PROPOSED LABEL:

<u>Active Ingredients:</u>	<u>% by weight</u>
Copper ethanolamine complex	14.61
Disodium octaborate tetrahydrate	12.50
<u>Other Ingredient(s):</u>	<u>72.89</u>
Total:	100.00

BACKGROUND

In support of registration of the subject product ORD-X021, EPA File Symbol 75341-RA, the applicant has submitted studies for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, eye irritation, skin irritation, and skin sensitization – MRIDs 488846-03 through -08, respectively.

DP 403967 - Page 1 of 13

PDF check WP  
11/9/12

## RECOMMENDATION

The submitted studies are acceptable. The resulting acute Toxicity Categories are listed in the table below.

### Summary:

The acute toxicity profile of ORD-X021 is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	488846-03	III	Acceptable
Acute Dermal Toxicity	488846-04	IV	Acceptable
Acute Inhalation Toxicity	488846-05	III	Acceptable
Primary Eye Irritation	488846-06	III	Acceptable
Primary Skin Irritation	488846-07	II	Acceptable
Dermal Sensitization	488846-08	Sensitizer	Acceptable

## PRODUCT LABELING

The following comments refer to the proposed draft label dated by applicant “JUN-2012” (EPA received 7/12/2012).

### Revisions:

The following changes should be made to the “Hazards to Humans and Domestic Animals” statements, in accordance with the *Label Review Manual*:

1. Add the statement: “Causes skin irritation.”
2. Add: “Harmful if inhaled. Avoid breathing vapor.”
3. Change the skin portion of the statement “Avoid contact with skin, eyes or clothing” so that it reads: “Do not get on skin or on clothing. Avoid contact with eyes.” (An alternative would be: “Do not get in eyes, on skin or clothing.”)

The following statements should be added to the First Aid section:

If inhaled:

Move person to fresh air.

If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

Call a poison control center or doctor for further treatment advice.

In the First Aid section, the "If on skin" instructions should be listed first. (The *Label Review Manual* states: "First Aid statements should be organized so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first.")

Other comments:

The statements for Personal Protective Equipment and for User Safety appear acceptable in light of existing Reregistration Eligibility Decision (RED) documents (the *Boric Acid* and *Coppers* REDs).

The Reregistration Eligibility Decision (RED) for *Coppers* contains a "General Application Restrictions for products with WPS or non-WPS uses on the label," to be placed in the Directions for Use (following the misuse statement). The Agency Product Manager may determine whether that statement is applicable and required:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation."

Information regarding the product (ORD-X021) has been entered into the Label Review System (LRS). The resulting sample labeling for the product in LRS is available for internal reference.

## DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OPPTS 870.1100)

**Product Manager:** 34  
**MRID No.:** 488846-03

**Reviewer:** W. Powell  
**Study Completion Date:** 4/19/2012  
**Report No.:** 33786

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Shaken prior to dosing.)  
**Dosage:** 175, 550, and 2,000 mg/kg

**Species:** Rat, Sprague-Dawley derived  
**Sex:** 8 Females (nulliparous and non-pregnant)  
**Age:** 8-11 weeks  
**Weight:** 165-205 g  
**Source:** Harlan Laboratories, Inc.

**Method:** Up-and-Down Procedure

### Summary:

1. **Estimated LD<sub>50</sub>:** 2,000 mg/kg
2. **Toxicity Category:** III
3. **Classification:** Acceptable

**Deviations from Guideline 870.1100:** None noted.

### Results:

The test substance was administered by oral gavage to eight female rats, in the sequence listed in the table below. Five reversals occurred in the last six animals tested, thus a stopping rule was met. The three decedent animals died within three hours after test substance administration.

A single dose was associated with partial response. This was the highest test dose, with no responses at all other test doses. This scenario corresponds to Case # 5 of Table 8 in section (m)(3) of the OPPTS 870.1100 Guidelines. Based on the *AOT425* software (Westat, May 2001) and the above scenario, the results indicate an acute oral LD<sub>50</sub> of 2,000 mg/kg. 95% PL Confidence Interval: 665.7 mg/kg to 4,540 mg/kg.

**Reported Mortality**

<b>Dosing Sequence</b>	<b>Animal No.</b>	<b>Dose Level (mg/kg)</b>	<b>Short-Term Outcome</b>	<b>Long-Term Outcome</b>
1	3101	175	S	S
2	3102	550	S	S
3	3103	2,000	S	S
4	3104	2,000	D	D
5	3105	550	S	S
6	3106	2,000	D	D
7	3107	550	S	S
8	3108	2,000	D	D

S = Survival, D = Death

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

**Product Manager:** 34  
**MRID No.:** 488846-04

**Reviewer:** W. Powell  
**Study Completion Date:** 4/11/2012  
**Report No.:** 33787

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Mixed prior to dosing. Dosed as received.)  
**Dosage:** 5,000 mg/kg

**Species:** Rat, Sprague-Dawley derived  
**Sex:** 5 Males, 5 Females (nulliparous and non-pregnant)  
**Age:** 9-10 weeks  
**Weight:** Males 252-268 g, Females 181-195 g  
**Source:** Harlan Laboratories, Inc.

**Summary:**

- 1. **Estimated LD<sub>50</sub>:** > 5,000 mg/kg
- 2. **Toxicity Category:** IV
- 3. **Classification:** Acceptable

**Deviations from Guideline 870.1200:** None noted.

**Results:**

Administration of the test substance by dermal application at a dose of 5,000 mg per kg body weight to male and female rats produced no mortality during the 14-day observation period. The results indicate that the dermal LD<sub>50</sub> of the sample was greater than 5,000 mg/kg in male and female rats. Clinical signs observed were limited to dermal irritation (erythema), small areas of eschar and/or blanching, and green staining. Necropsy revealed no gross abnormalities. All animals showed weekly weight gain.

Reported Mortality

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Combined
5,000	0 / 5	0 / 5	0 / 10



## DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)

**Product Manager:** 34  
**MRID No.:** 488846-05

**Reviewer:** W. Powell  
**Study Completion Date:** 4/19/2012  
**Report No.:** 33788

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Shaken prior to dispensing and kept on a magnetic stirrer.)  
**Concentration:** Gravimetric = 2.10 mg/L, Nominal = 32.06 mg/L. (Nose-only exposure)

**Species:** Rat, Sprague-Dawley derived  
**Sex:** 5 Males, 5 Females (nulliparous and non-pregnant)  
**Age:** 9-10 weeks  
**Weight:** Males 256-273 g, Females 175-190 g  
**Source:** Harlan Laboratories

### Summary:

1. **LC<sub>50</sub> (mg/L):** > 2.10 mg/L in male rats,  
> 0.5 mg/L in female rats
2. **Average MMAD:** 2.31  $\mu$ m
3. **Toxicity Category:** III
4. **Classification:** Acceptable

### Deviations from Guideline 870.1300:

1. After what appeared to be compound-related mortality in two females occurred at one dose concentration, a second concentration was not tested. (Refer to *Results* below for further details.)
2. It appears that the total volume of the animals was greater than 5% of the chamber volume. However, in view of the plentiful airflow rate, this is not a concern.

### Results:

Two (of five) females died. The one was found dead approximately 3.5 hours post-exposure; the other was euthanized for humane reasons. The other 3 females and all 5 males survived the 14-day observation period.

Following exposure, all animals exhibited irregular respiration. Several exhibited hypoactivity and rales (moist). In addition, one of the two decedents exhibited tremors, and the other exhibited ataxia, proneness, gasping, and moribund appearance. The surviving animals recovered from the reported symptoms at various times ranging from Day 2 to Day 10.

Necropsy findings were unremarkable except in the two decedents. In one of the decedents was found discoloration and distension of the stomach and intestines and darkened spots on the liver and kidneys. In the other decedent was found discoloration of the lungs.

Based on the reported mortality, the median lethal concentration is estimated to be greater than 2.10 mg/L in male rats. However, in female rats the median lethal concentration is considered undetermined, though for regulatory categorization it is being considered greater than 0.5 mg/L (as a worst case).

In order to qualify as a limit test, mortality should be limited to no more than one animal in either sex. This study is no exception, as the two deaths in the female seem compound-related. The ORD-X021 study, then, does not qualify as a limit test. I.e., we cannot assign 2.10 mg/L as the LC<sub>50</sub> lower limit or place the test material in Toxicity Category IV for acute inhalation. Category III is assigned as worst case (as a Category II outcome would be very unlikely).

**Reported Mortality**

Exposure Concentration (mg/L)	Number of deaths / number tested		
	Males	Females	Combined
2.10	0 / 5	2 / 5	2 / 10

**Chamber Atmosphere**

Exposure Conc. (mg/L)	MMAD (µm)	GSD (µm)	% of Particles ≤ 4.7 µm
2.10	2.31	2.29	82.8

**Chamber Environment**

Exposure Level (mg/L)	2.10
Chamber Volume, approx. (L)	28
Total Airflow Rate (Lpm)	31.6
Temperature in exposure tube (°C)	19 - 20
Relative Humidity in exposure tube (%)	26 - 32

## DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

**Product Manager:** 34  
**MRID No.:** 488846-06

**Reviewer:** W. Powell  
**Study Completion Date:** 4/19/2012  
**Report No.:** 33789

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Shaken prior to dosing.)  
**Dosage:** 0.1 mL

**Species:** Rabbit, New Zealand albino  
**Sex:** 3 females (nulliparous and non-pregnant)  
**Age:** Young adult  
**Weight:** Not reported  
**Source:** Robinson Services, Inc.

### Summary:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

**Deviations from Guideline 870.2400:** The study report did not state that the lids of the treated eye were held together for about 1 second following test substance instillation. (However, the Study Director Carolyn Lowe told the reviewer on 10/22/2012 that this procedural step is always taken.)

### Results:

Corneal opacity (of low degree, grade 1 on the Draize scale) and ‘positive’ conjunctival redness and swelling (both of grade 2), were observed in two of three rabbits at 1 hour, and positive conjunctival redness in one of three rabbits at 24 hours. All such signs cleared in all rabbits by 48 hours. No iridal involvement or other positive signs were observed during the 72-hour observation period.

### Incidence of Irritation

Time Post-Instillation	No. of Animals Testing “Positive” / No. of Animals Tested			
	Corneal Opacity	Iritis	Conjunctiva	
			Redness	Chemosis
1 hour	0 / 3	0 / 3	3 / 3	3 / 3
24 hours	1 / 3	0 / 3	1 / 3	0 / 3
48 hours	0 / 3	0 / 3	0 / 3	0 / 3
72 hours	0 / 3	0 / 3	0 / 3	0 / 3

## DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OPPTS 870.2500)

**Product Manager:** 34  
**MRID No.:** 488846-07

**Reviewer:** W. Powell  
**Study Completion Date:** 4/19/2012  
**Report No.:** 33790

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021. (Shaken prior to dosing.)  
**Dosage:** 0.5 mL

**Species:** Rabbit, New Zealand albino  
**Sex:** 3 females (nulliparous and non-pregnant)  
**Age:** Young adult  
**Weight:** Not reported  
**Source:** Robinson Services, Inc.

### Summary:

1. **Toxicity Category:** II
2. **Classification:** Acceptable

**Deviations from Guideline 870.2500:** None noted.

### Results:

Two of three animals showed very slight erythema and no edema. Erythema in the third animal was well-defined at 30 to 60 minutes after patch removal and was severe from 24 hours through Day 7. In this animal, a small area of eschar was observed at the dose site from 24 hours through Day 7, and desquamation was observed at the dose site on Days 7 and 10.

The Guidelines define the skin irritation Toxicity Category in terms of the effects at 72 hours. In view of that, and in view of the small number of animals tested, and the severity of response in animal 3503 and its lack of improvement until late in the study, a strong emphasis is being placed on animal 3503. The severe irritation in that animal cleared after Day 7. In view of all this, Toxicity Category II is assigned (even though the study report states that the requirements of Category IV were met, a conclusion that may have been based in large part on the Primary Irritation Index).

Individual Skin Irritation Scores

Animal No.	Sex	Erythema / Edema					
		Time After Patch Removal					
		30-60 min	24 hrs	48 hrs	72 hrs	Day 7	Day 10
3501	F	1 / 0	1 / 0	0 / 0	0 / 0	0 / 0	0 / 0
3502	F	1 / 0	1 / 0	0 / 0	0 / 0	0 / 0	0 / 0
3503	F	2 / 1 <sup>1</sup>	4 / 2 <sup>2</sup>	4 / 1 <sup>2</sup>	4 / 1 <sup>2</sup>	4 / 1 <sup>2,3</sup>	0 / 0 <sup>3</sup>

<sup>1</sup> Blue discoloration in the dose site

<sup>2</sup> Small area of eschar in the dose site

<sup>3</sup> Desquamation present at the dose site

## DATA REVIEW FOR SKIN SENSITIZATION TESTING (OPPTS 870.2600)

**Product Manager:** 34  
**MRID No.:** 488846-08

**Reviewer:** W. Powell  
**Study Completion Date:** 4/10/2012  
**Report No.:** 33791

**Testing Laboratory:** Product Safety Labs – Dayton, NJ  
**Author:** Carolyn Lowe

**Quality Assurance (40 CFR §160):** Included

**Test Material:** ORD-X021 (a dark blue liquid)  
**Positive Control Material:** alpha-Hexylcinnamaldehyde

**Species:** Mouse, CBA/J, Female  
**Weight:** 18.7-23.3 g (Test and Control groups)  
**Age:** 10-11 weeks (Test and Control groups), 9-10 weeks (Preliminary animals)  
**Source:** Harlan Laboratories, Inc.

**Method:** Local Lymph Node Assay

### Summary:

1. ORD-X021 appeared to be a contact sensitizer.
2. **Classification:** Acceptable

### Deviations from Guideline 870.2600:

- Temperature in the animal room slightly exceeded the Guidelines.
- Based on body weights reported, it appears that the Vehicle Control and Positive Control animals were the same as those used in Product Safety Labs study 33785 (MRID 488852-08, reviewed in Data Package 404722). Presumably this is because (as appears to be the case) the two studies were conducted concurrently and the Vehicle Control and Positive Control substances appear appropriate for both studies. Thus the sharing of these animals between the two studies was appropriate.

### Procedure:

Five female mice were selected for one Test Substance group. (No further Test Substance groups were treated, presumably because this group showed a positive response.) On Days 1, 2, and 3, 25 µL of a 25% concentration of the test substance in propylene glycol was applied to the dorsum of both ears of each test animal. A Vehicle Control group (5 females) was treated in the same way as the Test Substance group, but with vehicle alone (propylene glycol). A Positive Control group (5 females) was treated with 25% alpha-hexylcinnamaldehyde in propylene glycol. The test sites in all three groups were evaluated for local irritation (erythema & edema) on Days 1, 2, 3, and 6. Body weights were taken on Days 1 and 6.

On Day 6, the animals in all three groups were injected in the tail vein with 250 µL of phosphate buffered saline (PBS) containing 20 µCi of <sup>3</sup>H-methyl thymidine. Approximately five hours after the injection, the draining auricular lymph nodes were excised and pooled for each mouse.

A single cell suspension of lymph node cells was prepared in PBS by massaging the lymph nodes between frosted ends of two microscope slides over a collection vessel. The contents of the vessel were transferred to a centrifuge tube, washed with an excess of PBS, and centrifuged for approximately 10 minutes at 1800 rpm. This wash and centrifuge was carried out twice. The supernatant was decanted and discarded following each centrifugation. After the second wash, approximately 5 mL of 5% trichloroacetic acid (TCA) was added to the sediment and the tube was briefly vortexed. The DNA was then precipitated in the TCA at approximately 4.1-4.2 °C for approximately 18 hours. The tubes were centrifuged again. The resulting precipitate was re-suspended in TCA and transferred to 10 mL of scintillation fluid. Incorporation of <sup>3</sup>H-methyl thymidine was measured by B-scintillation counting and expressed as disintegrations per minute (DPM) minus background DPM.

**Results:**

Stimulation Index (SI) for Test Substance group and for Positive Control group was derived by dividing the average net DPM of each group by the average net DPM of the Vehicle Control group, where “net DPM” is the measured DPM minus the background DPM.

Animal Group	Test Substance Concentration	Average Net DPM	Number of Mice	SI
Vehicle Control	N/A	965.39	5	N/A
Positive Control	N/A	4713.56	5	4.88
Test Substance	25%	8927.23	5	9.25

An SI far greater than 3.0 was observed in the Test Substance group, thus indicating that ORD-X021 tested positive for dermal sensitization. Note: Only slight skin irritation effects were observed in the Test Substance group. The Positive Control group tested positive.







July 10, 2012

Document Processing Desk (APPLY)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Re: ORD-X021  
Application for Product Registration

Dear Sir/Madam:

Enclosed is an application for the registration of ORD-X021. This application is for a new end-use label using EPA registered technical active ingredients. The selective method of support has been selected. In support of this application, I am forwarding the following listed materials:

1. Application for Pesticide Registration, EPA Form 8570-1
2. Confidential Statement of Formula, EPA Form 8570-4
3. Formulator's Exemption Statement, EPA Form 8570-27
4. Certification with Respect to Citation of Data, EPA Form 8570-34
5. Data Matrix, EPA Form 8570-35
6. Five (5) copies of the product label
7. Three (3) copies of each of the following listed studies:
  - Muchow, Teri, 2012, ORD-X021 Product Chemistry Data. Unpublished study by Osmose, Inc. 51 pages. With Confidential Attachment.
  - Johnson, Lisa, 2011, Physical and Chemical Characteristics of ORD-X021. Unpublished study by Analytical & Regulatory Chemistry, Inc. 11 pages.
  - Lowe, Carolyn, 2012, Acute Oral Toxicity Up and Down Procedure in Rats. Unpublished study by Eurofins PSL. 15 pages.
  - Lowe, Carolyn, 2012, Acute Dermal Toxicity in Rats. Unpublished study by Eurofins PSL. 16 pages

Osmose, Inc.  
1016 Everree Inn Road • P.O. Box O • Griffin, GA 30224-0249  
770-233-4200 • Fax 770-229-5225

TRANSMITTAL DOCUMENT

Name and Address of Submitter: Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, NY 14209

Regulatory action in support of which this package is submitted: Application for Registration of ORD-X021 with data

EPA Reg. No./File Symbol: 75341-xx

Alternate Test Material Names: Studies are all under the product name ORD-X029

Transmittal Date: July 10, 2012

Administrative Materials	
	Transmittal Document
	Cover Letter
EPA Form 8570-1	Application for Pesticide Registration
EPA Form 8570-4	Confidential Statement of Formula
EPA Form 8570-27	Formulator's Exemption Statement
EPA Form 8570-34	Citation of Data
EPA Form 8570-35	Data Matrix
	Product Label (5 copies)

Citation	MRID Number
Muchow, Teri, 2012, ORD-X021 Product Chemistry Data. Unpublished study by Osmose, Inc. 51 pages. With Confidential Attachment.	48884601
Johnson, Lisa, 2011, Physical and Chemical Characteristics of ORD-X021. Unpublished study by Analytical & Regulatory Chemistry, Inc. 11 pages.	48884602
Lowe, Carolyn, 2012, Acute Oral Toxicity Up and Down Procedure in Rats. Unpublished study by Eurofins PSL. 15 pages.	48884603
Lowe, Carolyn, 2012, Acute Dermal Toxicity in Rats. Unpublished study by Eurofins PSL. 16 pages	48884604
Lowe, Carolyn, 2012, Acute Inhalation Toxicity in Rats. Unpublished study by Eurofins PSL. 22 pages	48884605
Lowe, Carolyn, 2012, Primary Eye Irritation Study in Rabbits. Unpublished study by Eurofins PSL. 15 pages	48884606
Lowe, Carolyn, 2012, Primary Skin Irritation in Rabbits. Unpublished study by Eurofins PSL. 15 pages	48884607
Lowe, Carolyn, 2012, Local Lymph Node Assay (LLNA) in Mice. Unpublished study by Eurofins PSL. 21 pages	48884608

**OSMOSE UTILITIES SERVICES, INC.**  
**980 Ellicott Street**  
**Buffalo, NY 14209**

---

**Company Official:** Teri Muchow, Manager – Regulatory Administration

**Company Name:** Osmose Utilities Services, Inc.

**Company Contact:** Teri Muchow  
Manager – Regulatory Administration  
Phone #: 770-233-4244  
Fax #: 770-229-5225  
Email: [tmuchow@osmose.com](mailto:tmuchow@osmose.com)

# DATA PACKAGE BEAN SHEET

Date: 24-Jul-2012

Page 1 of 2

Decision #: 467215

DP #: (403966)

PRIA

Parent DP #:

Submission #: 920019

E-Sub #:

## \*\*\* Registration Information \*\*\*

Registration: 75341-RA - ORD-X021

Company: 75341 - OSMOSE UTILITIES SERVICES, INC.

Risk Manager: RM 34 - Jacqueline Campbell-McFarlane - (703) 308-6416 Room# PY1 S-82

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: \_\_\_\_\_

PRIA Due Date: 07-Dec-2012

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: 024409, Copper ethanolamine complex(14.61%)

011107, Boron sodium oxide (B8Na2O13) (12008-41-2)(12.5%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☒ Yes ☐ No

Date Sent: 24-Jul-2012

Due Back: \_\_\_\_\_

DP Ingredient: 011107, Boron sodium oxide (B8Na2O13) (12008-41-2)

024409, Copper ethanolamine complex

DP Title: Product Chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: \_\_\_\_\_

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 07-Nov-2012

Team Name: CTT

Science Due Date: \_\_\_\_\_

Reviewer Name: Chris

7/27/12

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

New Wood Preservative Product

Please review the chemistry data in MRID 488884601 thru 48884602

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 7-12-12  
 Experts In-Processing Signature: MF Harrington Date 7-17-12 Fee Paid: Yes \_\_\_  
 Division management contacted on issues No \_\_\_ Yes \_\_\_ Date \_\_\_

EPA Reg. Number: <u>75341-RA</u>		EPA Receipt Date: <u>7-12-12</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)			X		
		yes	no			
		X				
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
		yes	no			
	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) <b>(Electronic labels on CD are encouraged and guidance is available)</b> ( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			



site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/opbpbpd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/opbpbpd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

July 16, 2012

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-467215  
EPA File Symbol or Registration Number: 75341-RA  
Product Name: ORD-X021  
EPA Receipt Date: 12-Jul-2012  
EPA Company Number: 75341  
Company Name: OSMOSE UTILITIES SERVICES, INC.

TERI MUCHOW  
OSMOSE UTILITIES SERVICES, INC.  
980 ELLICOTT STREET  
BUFFALO, NY 14209

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

A handwritten signature in black ink, appearing to be "m. zla", is written over the typed name of the Front End Processing Staff.

Front End Processing Staff  
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

July 16, 2012

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-467215  
EPA File Symbol or Registration Number: 75341-RA  
Product Name: ORD-X021  
EPA Receipt Date: 12-Jul-2012  
EPA Company Number: 75341  
Company Name: OSMOSE UTILITIES SERVICES, INC.

TERI MUCHOW  
OSMOSE UTILITIES SERVICES, INC.  
980 ELLICOTT STREET  
BUFFALO, NY 14209

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

A handwritten signature in black ink, appearing to be "m. zla", is written over the typed name.

Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

{920019Ê~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☒ AD

☐ BPPD

☐ RD

Risk Mgr.

34

Receipt No.

S-

920019

EPA File Symbol/Reg. No.

75341-RA

Pin-Punch Date:

7/12/2012

☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

A540

Granted:

A540

Amount Due: \$ 4631<sup>00</sup>

## Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Team 3

Date: 07/13/2012

Remarks:

Receipt for Section 3

S: 920019

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 75341 OSMOSE UTILITIES SERVICES, INC.

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 75341-RA

Product Name: ORD-X021

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 10-Jul-2012

Front End Date: 12-Jul-2012

FFS Due Date:

OPP Target Date:

Fast Track:

Receipt Description: Application for product registration

Form A:

Signature Date:

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

V

OPP Rec'vd Date: 12-Jul-2012

Risk Manager Send Date:

Negotiated Due Date:

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Signature Date:

View/Edit

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF



Check No. 115452

[illegible]

\*Commercial/financial information may be entitled to confidential treatment\*

WARNING: DO NOT ACCEPT THIS DOCUMENT UNLESS YOU CAN SEE A TRUE WATERMARK AND VISIBLE FIBERS FROM BOTH SIDES.

**Osmose®**  
980 Ellicott Street  
Buffalo, NY 14209

**M & T TRUST CO.**  
Northeast Business Center  
Newburgh, NY 12550  
10-4/220

115452

**Void 6 Months After Date**

Date Jun/19/2012

Pay Amount \$4,631.00\*\*\*

Pay \*\*\*\*FOUR THOUSAND SIX HUNDRED THIRTY-ONE AND XX / 100 US DOLLAR\*\*\*\*

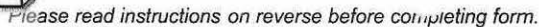
**To The  
Order Of**

**ENVIRONMENTAL PROTECTION AGENCY**

U.S. Bank  
Government Lockbox 979074  
1005 Convention Plaza- SL-MO-C2-GL  
St. Louis, MO 63197  
USA

\_\_\_\_\_  
AUTHORIZED SIGNATURE

11 1 1 5 4 5 2 11 1:0 2 2 0 0 0 0 4 6 1:



EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

July 10, 2012

Document Processing Desk (APPLY)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Re: ORD-X021  
Application for Product Registration

Dear Sir/Madam:

Enclosed is an application for the registration of ORD-X021. This application is for a new end-use label using EPA registered technical active ingredients. The selective method of support has been selected. In support of this application, I am forwarding the following listed materials:

1. Application for Pesticide Registration, EPA Form 8570-1
2. Confidential Statement of Formula, EPA Form 8570-4
3. Formulator's Exemption Statement, EPA Form 8570-27
4. Certification with Respect to Citation of Data, EPA Form 8570-34
5. Data Matrix, EPA Form 8570-35
6. Five (5) copies of the product label
7. Three (3) copies of each of the following listed studies:
  - Muchow, Teri, 2012, ORD-X021 Product Chemistry Data. Unpublished study by Osmose, Inc. 51 pages. With Confidential Attachment.
  - Johnson, Lisa, 2011, Physical and Chemical Characteristics of ORD-X021. Unpublished study by Analytical & Regulatory Chemistry, Inc. 11 pages.
  - Lowe, Carolyn, 2012, Acute Oral Toxicity Up and Down Procedure in Rats. Unpublished study by Eurofins PSL. 15 pages.
  - Lowe, Carolyn, 2012, Acute Dermal Toxicity in Rats. Unpublished study by Eurofins PSL. 16 pages

OSMOSE UTILITIES SERVICES, INC.  
980 Ellicott Street  
Buffalo, NY 14209

### TRANSMITTAL DOCUMENT

**Name and Address of Submitter:** Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, NY 14209

**Regulatory action in support of which this package is submitted:** Application for Registration of ORD-X021 with data

**EPA Reg. No./File Symbol:** 75341-xx

**Alternate Test Material Names:** Studies are all under the product name ORD-X029

**Transmittal Date:** July 10, 2012

---

#### **Administrative Materials**

---

	Transmittal Document
	Cover Letter
EPA Form 8570-1	Application for Pesticide Registration
EPA Form 8570-4	Confidential Statement of Formula
EPA Form 8570-27	Formulator's Exemption Statement
EPA Form 8570-34	Citation of Data
EPA Form 8570-35	Data Matrix
	Product Label (5 copies)

Citation	MRID Number
Muchow, Teri, 2012, ORD-X021 Product Chemistry Data. Unpublished study by Osmose, Inc. 51 pages. With Confidential Attachment.	_____
Johnson, Lisa, 2011, Physical and Chemical Characteristics of ORD-X021. Unpublished study by Analytical & Regulatory Chemistry, Inc. 11 pages.	_____
Lowe, Carolyn, 2012, Acute Oral Toxicity Up and Down Procedure in Rats. Unpublished study by Eurofins PSL. 15 pages.	_____
Lowe, Carolyn, 2012, Acute Dermal Toxicity in Rats. Unpublished study by Eurofins PSL. 16 pages	_____
Lowe, Carolyn, 2012, Acute Inhalation Toxicity in Rats. Unpublished study by Eurofins PSL. 22 pages	_____
Lowe, Carolyn, 2012, Primary Eye Irritation Study in Rabbits. Unpublished study by Eurofins PSL. 15 pages	_____
Lowe, Carolyn, 2012, Primary Skin Irritation in Rabbits. Unpublished study by Eurofins PSL. 15 pages	_____
Lowe, Carolyn, 2012, Local Lymph Node Assay (LLNA) in Mice. Unpublished study by Eurofins PSL. 21 pages	_____

**OSMOSE UTILITIES SERVICES, INC.**  
**980 Ellicott Street**  
**Buffalo, NY 14209**

---

**Company Official:** Teri Muchow, Manager – Regulatory Administration

**Company Name:** Osmose Utilities Services, Inc.

**Company Contact:** Teri Muchow  
Manager – Regulatory Administration  
Phone #: 770-233-4244  
Fax #: 770-229-5225  
Email: [tmuchow@osmose.com](mailto:tmuchow@osmose.com)



United States  
**Environmental Protection Agency**  
 Washington, DC 20460  
**Formulator's Exemption Statement**  
 (40 CFR 152.85)

Applicant's Name and Address  Osmose Utilities Services, Inc. 980 Ellicott Street Buffalo, NY 14209	EPA File Symbol/Registration Number 75341-
	Product Name ORD-X021
	Date of Confidential Statement of Formula (EPA Form 8570-4) 06/20/2012

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Copper Ethanolamine Complex, CAS #14215-52-2  
 Disodium Octaborate Tetrahydrate, CAS #12008-41-2

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Copper Ethanolamine Complex		
Disodium Octaborate Tetrahydrate		
Disodium Octaborate Tetrahydrate		
Disodium Octaborate Tetrahydrate		
Disodium Octaborate Tetrahydrate		
Signature	Name and Title Teri Muchow, Mgr-Regulatory Adm	Date 06/20/2012

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA  
 Copy 2 – Applicant copy

\*Product ingredient source information may be entitled to confidential treatment\*



United States  
**Environmental Protection Agency**  
 Washington, DC 20460  
**Formulator's Exemption Statement**  
*(40 CFR 152.85)*

Applicant's Name and Address

Osmose Utilities Services, Inc.  
 980 Ellicott Street  
 Buffalo, NY 14209

EPA File Symbol/Registration Number

75341-

Product Name

ORD-X021

Date of Confidential Statement of Formula (EPA Form 8570-4)

06/20/2012

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Copper Ethanolamine Complex, CAS #14215-52-2  
 Disodium Octaborate Tetrahydrate, CAS #12008-41-2

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:


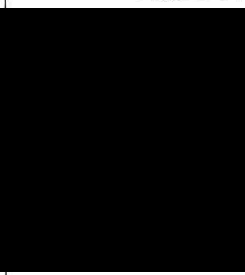
☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

## Source

Active Ingredient	Product Name	Registration Number
Copper Ethanolamine Complex		
Disodium Octaborate Tetrahydrate		
Disodium Octaborate Tetrahydrate		
Disodium Octaborate Tetrahydrate		
Disodium Octaborate Tetrahydrate		
Signature	Name and Title	Date
	Teri Muchow, Mgr-Regulatory Adm	06/20/2012

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
 Copy 2 - Applicant copy

\*Product ingredient source information may be entitled to confidential treatment\*





United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address  Osmose Utilities Services, Inc. 980 Ellicott Street Buffalo, NY 14209	EPA File Symbol/Registration Number 75341-
	Product Name ORD-X021
	Date of Confidential Statement of Formula (EPA Form 8570-4) 06/20/2012

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Copper Ethanolamine Complex, CAS #14215-52-2  
 Disodium Octaborate Tetrahydrate, CAS #12008-41-2

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Copper Ethanolamine Complex		
Disodium Octaborate Tetrahydrate		
Disodium Octaborate Tetrahydrate		
Disodium Octaborate Tetrahydrate		
Disodium Octaborate Tetrahydrate		
Signature	Name and Title Teri Muchow, Mgr-Regulatory Adm	Date 06/20/2012

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy

\*Product ingredient source information may be entitled to confidential treatment\*



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Osmose Utilities Services, Inc., 980 Ellicott St., Buffalo, NY 14209 phone: 716-882-5905	EPA Registration Number/File Symbol 75341-
Active Ingredient(s) and/or representative test compound(s) Copper Ethanolamine Complex and Disodium Octaborate Tetrahydrate	Date June 20, 2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial, out-doors, non-food use	Product Name ORD-X021

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Teri Muchow</i>	Date 06-20-2012	Typed or Printed Name and Title Teri Muchow, Manager Regulatory Administration
------------------------------	--------------------	---

## A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	+		
830.1600	Description of materials used to produce the product	X		
830.1650	Description of formulation process	+		
830.1670	Discussion on the formation of impurities	+		
830.1700	Preliminary analysis	X		
830.1750	Certified limits (158.345)	X		
830.1800	Enforcement analytical method	X		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	+		
830.6303	Physical State	X		
830.6304	Odor	X		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	X		
830.6315	Flammability	+		
830.6316	Explodability	X		
830.6317	Storage stability*	X		
830.6319	Miscibility	+		
830.6320	Corrosion Characteristics*	X		
830.6321	Dielectric Breakdown Voltage	X		
830.7000	pH	X		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	X		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	X		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required

\*May not be included with initial application

## A540 – Acute Toxicity Requirements

New products must either:

- 1) supply the product specific acute toxicity 6 pack data (listed below),
- 2) provide a bridging rationale document or waiver request or,
- 3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)	2			
830.1200	Acute Dermal (LD50)	x			
830.1300	Acute Inhalation (LC50)	x			
830.2400	Acute Eye Irritation	x			
830.2500	Acute Dermal Irritation	x			
830.2600	Dermal Sensitization	x			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 6/20/2012		EPA Reg No./File Symbol 75341-		Page 1 of 2	
Applicant's/Registrant's Name & Address Osmose Utilities Services, Inc., 980 Ellicott Street, Buffalo, NY 14209		Product ORD-X021			
Ingredient Copper Ethanolamine Complex and Disodium Octaborate Tetrahydrate					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition		Osmose Utilities Services, Inc.	OWN	
830.1600	Description of Starting Materials		Osmose Utilities Services, Inc.	OWN	
830.1650	Description of the Formulation Process		Osmose Utilities Services, Inc.	OWN	
830.1670	Discussion of Formation of Impurities		Osmose Utilities Services, Inc.	OWN	
830.1750	Certified Limits		Osmose Utilities Services, Inc.	OWN	
830.1800	Enforcement Analytical Methods		Osmose Utilities Services, Inc.	OWN	
830.6302	Color		Osmose Utilities Services, Inc.	OWN	
830.6303	Physical State		Osmose Utilities Services, Inc.	OWN	
830.6304	Odor		Osmose Utilities Services, Inc.	OWN	
830.6314	Oxidizing or reducing action		Osmose Utilities Services, Inc.	OWN	
830.7000	pH		Osmose Utilities Services, Inc.	OWN	
830.7100	Viscosity		Osmose Utilities Services, Inc.	OWN	
830.7300	Density/relative density		Osmose Utilities Services, Inc.	OWN	
Signature <i>Teri Muchow</i>			Name and Title Teri Muchow, Manager, Regulatory Administration		Date 06/20/2012



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling. Shake before using. Dilute 1 gallon of this concentrate with 1 ½ gallons of water. If diluted product is to be used or stored at temperatures near or below 32°F (0°C), dilute 1 gallon of this concentrate with ¾ of a gallon (2840 ml) of water and ¼ of a gallon (2840 ml) of propylene glycol to prevent freezing. Shake or stir well before using.

**Internal Treatment:** Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening. Apply one gallon (maximum per cu. ft. of wood) or to refusal.

**Surface Treatment:** ORD-X021 can also be applied by brush or roller to protect wood surfaces or end-cuts. Use one coat on materials to be finished with paint or stain. If no finish is to be used, apply two liberal coats within the hour. Thoroughly cover ends.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in a secure, well-ventilated area protected from extreme temperatures. Do not transfer to unmarked containers. Keep container closed when not in use.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent) promptly after emptying. Puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**DRUMS:** Residue Removal: Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat the procedure two more times. Offer for reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**CONTAINERS 5 GALLONS OR LESS:** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, New York 14209  
EPA Est. 3008-NY-1  
E.P.A. Registration No. 75341-xx

INDUSTRIAL USE ONLY. NOT FOR HOUSEHOLD USE

ORD-X021

ACTIVE INGREDIENTS:

Copper Ethanolamine Complex*.....	14.61%
(CAS No. 14215-52-2).	
Disodium Octaborate Tetrahydrate .....	12.5%
Inert Ingredients.....	72.89%
TOTAL	100.00%

\*Equivalent to 5% Copper as Metal

FOR EXTERIOR USE ONLY  
KEEP OUT OF REACH OF CHILDREN  
CAUTION

FIRST AID

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed:	Call poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Probable mucosal damage may contraindicate the use of gastric lavage.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
To report complaints, or in case of accidents or medical emergencies involving this product, call CHEMTREC at 1-800-424-9300.	

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS: \_\_\_\_\_

BATCH NO: \_\_\_\_\_

DESCRIPTION

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling.

PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment

Applicators and other handlers must wear eye protection, such as goggles or face shield, and chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, vitro). Mixers, loaders, applicators, and other handlers must wear the following: long-sleeve shirt or protective sleeves, long pants, shoes plus socks. Protective clothing must be changed when it shows signs of contamination. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

User Safety Recommendations

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

JUN-2012

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timber and piling. Shake before using. Dilute 1 gallon of this concentrate with 1 ½ gallons of water. If diluted product is to be used or stored at temperatures near or below 32°F (0°C) dilute 1 gallon of this concentrate with ¾ of a gallon (2840 ml) of water and ¼ of a gallon (2840 ml) of propylene glycol to prevent freezing. Shake or stir well before using.

**Internal Treatment:** Using air or mechanical pressure pump, apply solution to interior cavity of wood structure through prepared opening. Apply one gallon (maximum per cu. ft. of wood) or to refusal.

**Surface Treatment:** ORD-X021 can also be applied by brush or roller to protect wood surfaces or end-cuts. Use one coat on materials to be finished with paint or stain. If no finish is to be used, apply two liberal coats within the hour. Thoroughly cover ends.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in a secure, well-ventilated area protected from extreme temperatures. Do not transfer to unmarked containers. Keep container closed when not in use.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse (or equivalent) promptly after emptying. Puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**DRUMS: Residue Removal:** Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat the procedure two more times. Offer for reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**CONTAINERS 5 GALLONS OR LESS:** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Osmose Utilities Services, Inc.  
980 Ellicott Street  
Buffalo, New York 14209  
EPA Est. 3008-NY-1  
E.P.A. Registration No. 75341-xx

INDUSTRIAL USE ONLY. NOT FOR HOUSEHOLD USE

ORD-X021

ACTIVE INGREDIENTS:

Copper Ethanolamine Complex*.....	14.61%
(CAS No. 14215-52-2).	
Disodium Octaborate Tetrahydrate .....	12.5%
Inert Ingredients.....	72.89%
TOTAL	100.00%

\*Equivalent to 5% Copper as Metal

FOR EXTERIOR USE ONLY  
KEEP OUT OF REACH OF CHILDREN  
CAUTION

FIRST AID

If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice
If swallowed:	Call poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.  Probable muscosal damage may contraindicate the use of gastric lavage.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
To report complaints, or in case of accidents or medical emergencies involving this product, call CHEMTREC at 1-800-424-9300.	

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS: \_\_\_\_\_

BATCH NO: \_\_\_\_\_

DESCRIPTION

ORD-X021 is designed for remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling.

PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Harmful if swallowed or absorbed through the skin.. Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment

Applicators and other handlers must wear eye protection, such as goggles or face shield, and chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, vitro). Mixers, loaders, applicators, and other handlers must wear the following: long-sleeve shirt or protective sleeves, long pants, shoes plus socks. Protective clothing must be changed when it shows signs of contamination. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

User Safety Recommendations

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

JUN-2012



FOR OFFICIAL USE ONLY

FILE SYMBOL

REGISTRATION NO.

75341 - RA

## CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
JUL 12 2012		

**Do Not Write Comments,  
Formula, or Parts of Formula  
on This Envelope**

### NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

